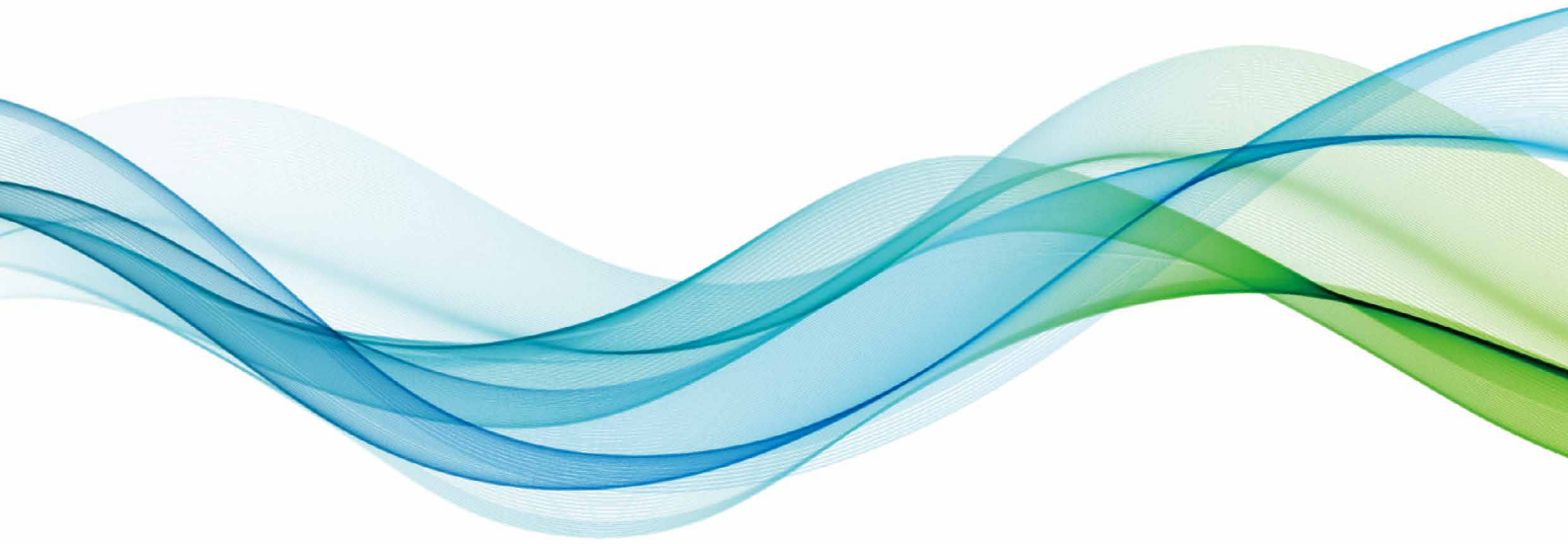
Strengthening Program for Pharmaceutical Startup Ecosystem



Japan Agency for Medical Research and Development

Strengthening Program for Pharmaceutical Startup Ecosystem

Program Outline

Most new drugs in recent years have been developed by pharmaceutical startups, and it is pharmaceutical startups that have succeeded in the development of vaccines early in the current pandemic. Although a large amount of money is required for the development of new drugs, it is difficult to secure the necessary development funds smoothly in Japan's pharmaceutical startup ecosystem compared to Europe and the United States.

In response to this situation, under the "Strategy for Strengthening Vaccine Development and Production Systems" approved by the Cabinet in June 2021, this Program was established to support pharmaceutical startup companies engaged in the commercialization and development of technologies related to vaccines and therapeutics for infectious diseases. Furthermore, in October 2022, the "Priority Issues in a Comprehensive Economic Package regarding the Implementation of the "Grand Design and Action Plan for a New Form of Capitalism"" stated that this Program "In the future, the government plans to expand the scope of support to drug discovery fields that are difficult to raise funds for, other than those related to infectious diseases."

In order to resolve the shortage of sources of development funds on a large scale, this Program registers VCs that provide hands-on commercialization support specializing in drug discovery, and supports the development and commercialization carried out by Pharmaceutical Startups in the development stage of non-clinical, phase 1, phase 2, or exploratory clinical trials, with the requirement of investment by the registered VCs (Hereinafter referred to as "Registered VC".), thereby raising the foundation of Japan's pharmaceutical startup ecosystem. In particular, we will actively support commercialization plans in overseas markets in addition to Japan in order to achieve sufficient sales and growth.

Program Supervisor (PS)

Former chairperson of Drug Evaluation Committee

Japan Pharmaceutical Manufacturers Association (JPMA)

INAGAKI Osamu

Program Officer (PO)

President

Gallasus, LLC

HASHIMOTO Chika

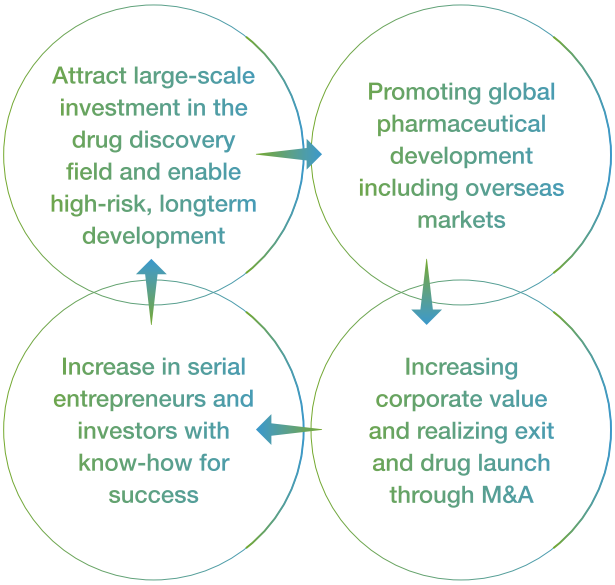
Chairman

SENSHIN Medical Research Foundation

HAYASHI Yoshiharu

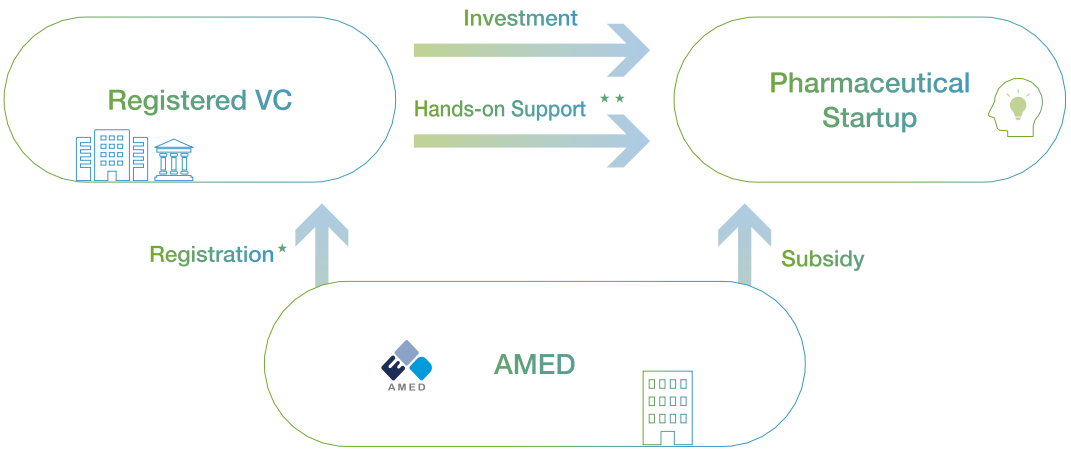
Program Objective

In order to strengthen the Pharmaceutical Startup Ecosystem in Japan, we aim to build the effective and synergistic cycle by creating as many successful examples of global standards as possible.



Program Scheme

In this Program, AMED subsidizes the practical development of pharmaceuticals conducted by Pharmaceutical Startups in which registered VCs invest more than 1/3 of total expenses covered by the Subsidy.
This Program makes two stages of calls for proposals, which are Call for Proposals for VC Registered by AMED (**(i)Call for Proposals for VC Registration**,) and Call for Proposals for the practical development of pharmaceuticals conducted by Pharmaceutical Startups invested by Registered VCs (**(ii)Call for Proposals from Pharmaceutical Startups**).



* Registration ..... Registration of VCs with track records of investment and support, etc. in the drug discovery field

** Hands-on Support ..... Support according to the growth stage of Pharmaceutical Startups from the perspectives on management, development and technology, and regulatory affairs

Contents

Call for Proposals for VC Registration

Requirements for certified VCs

- As a lead investor, invest more than 1 billion yen in the startup from the initial investment to the end of the Subsidized Project Period.
- Consistently support the startup as a lead investor during the Subsidized Project Period.

The definition of "lead" in this program is, in principle, the investor who has the largest amount of investment during the period covered by this program, and the investor who plays a leading role in fundraising and hands-on activities.

Registration Period

- 2 business years from the date of registration (Up to the end of the business year in which this program ends)
- An evaluation is conducted every 2 business years to determine whether or not registration can be renewed.
  No limit on number of renewals.

Evaluation Items

- Conformity to Program Objectives
- Sourcing capability
- Ability to carry out fundraising
- Hands-on capability

Mandatory Requirements

(ⅰ) Investing 1/3 or more of its total investment as a VC in the drug discovery field in the last 5 years.
(If the applicant has a fund specialized in investing in the drug discovery field, or if the applicant is evaluated as capable of providing particularly high-quality support to Pharmaceutical Startups in the evaluation items, the applicant will be considered for reviewing even if the applicant does not satisfy (ⅰ)).

(ⅱ) The applicant must have a track record of supporting clinical trials conducted by the Pharmaceutical Startup in which it has invested as a Lead VC.
(In the cases of a newly established VC or fund, the requirement (ⅱ) may be subject to review in light of the past performance of the individual[*1] to whom the VC belongs.)

(ⅲ) The applicant must have a track record of dispatching directors to the Pharmaceutical Startups in which it has invested as a Lead VC.
(In the case of a newly established VC or fund, the requirement (ⅲ) may be subject to review in light of the past performance of the individual[*1] to whom the VC belongs.)

(ⅳ) Members[*2] who make investment decisions or provide expert advice on investment decisions as hands-on members have experience in drug development at pharmaceutical companies, etc. (regulatory affairs, business development, development planning, etc.) or have important experience (review by organizations such as PMDA and FDA, etc.) in advancing drug development.

(ⅴ) Members[*2] who make investment decisions or provide expert advice on investment decisions as hands-on members have experience in global drug development (experience in conducting global clinical trials, experience in providing hands-on support for global clinical trials, etc.).

＊1 Members who make investment decisions or provide expert advice on investment decisions as hands-on members.
＊2 General partner, partner, etc.

Plan of call for Proposals

The Call for Proposals are scheduled to be held periodically several times a year.

＊Please check the latest Application Guidelines

List of Registered VCs

(As of August 2024)

Outlines of Registered VCs

ANV Management, LLC

Website

Contact info"AT"an.vc

Website https://an.vc/en/

AN Venture Partners (ANV), is a Tokyo- and San Francisco-based venture capital firm that invests in the life sciences sector. ANV was founded by a group of experienced Japanese and US venture capital (VC) professionals with extensive experience in startups and investment activities. While Japan generates a large amount of innovative scientific research, the Japanese ecosystem faces challenges in creating global companies based on these innovations. ANV was created as a VC firm to connect Japan and the world so that Japan can maximize its scientific potential. Specifically, ANV invests in promising research from Japanese universities and supports the commercialization of these ideas by creating companies in the US, including pre-startup and early-stage startup firms. By developing business in the US, which has a more mature ecosystem, deeper talent pool and far larger capital market, ANV hopes to grow these companies, leading to the efficient social implementation of their innovations. Ultimately, the aim is to hold an initial public offering (IPO) for these startups, for example on NASDAQ; or to achieve an exit via a sale to a global pharma company.

AN VENTURES

Person in charge


Ken Horne


FUTAMI Takashi


Ari Nowacek

Astellas Venture Management LLC

Website

Contact tadayoshi.hirata"AT"astellas.com

Website https://www.astellasventure.com/

AVM is the wholly-owned venture capital organization within Astellas, dedicated to supporting pre-clinical, cutting-edge science that can bring VALUE to patients. We make investments in privately owned early-stage biotechnology companies focused on therapeutics programs and platform technologies for discovery and development. After making investments, we provide "Pharma View," based on our long history and experience in the pharmaceutical industry. We also offer business support leveraging the expertise, experience, and global network of our team members to implement portfolio companies' innovations and delivery them to patients more swiftly.

astellas

Person in charge


HIRATA Tadayoshi


SAKURAI Nagisa


William Watt


Bradley Hardiman


KONAGAI Satoshi


MIYAKE Shinichi

Beyond Next Ventures Inc.

Website

Contact https://beyondnextventures.com/contact/

Website https://beyondnextventures.com/

We are a venture capital firm dedicated to addressing global challenges through the social implementation of innovative science and technology and the enhancement of ecosystems. Our team, specializing in the biopharmaceutical sector, includes capitalists, advisors, and an extensive external network (including partnered CROs), all working together to support the formation of management teams, the planning and execution of business, intellectual property, and partnership strategies, as well as domestic and international marketing and fundraising. Our goal is to reduce business risks and enhance business value. Additionally, we have established a shared wet lab, "Beyond BioLAB TOKYO," in Nihonbashi, Tokyo, to further support research and development in the life sciences sector.

Beyond Next Ventures

Person in charge


SAWABE Takehiko


YATO Keigo

*Replace “AT” with “@”.

Catalys Pacific, LLC

Website

Contact info“AT”catalyspacific.com

Website https://catalyspacific.com/

Catalys Pacific is an independent venture capital firm focusing on early-stage investments in life sciences. The firm’s mission is improving patient lives worldwide by driving impact and innovation in healthcare and contributing to advancements in life sciences. Founded in 2019, the firm acts as a trusted regional partner, building companies and catalyzing transpacific partnerships to fulfill its mission. The Catalys Pacific team is based in Tokyo, Japan and San Francisco, California.
Learn more at website.

CATALYS PACIFIC

Person in charge

TAKAHASHI Takeshi

NAGATA Megumi

D3LLC

Website

Contact info“AT”d3growth.com

Website https://www.d3growth.com/

D3 LLC is a Japanese venture capital firm specializing in bio-healthcare. Our investment professionals with a background in science (bio, med, pharma) and global business experience at McKinsey or US based VC/PE funds provide global standard bio-healthcare investments that have not been made in Japan before. We actively collaborate with investors and business companies in Japan and abroad, with the purpose of "contributing to global medical health from Japan". If you are an investor or a company that sees the potential of science and startups in Japan, please feel free to contact us.

D3 LLC
Discovery Development Deployment

Person in charge

NAGATA Tomoya

WATATANI Kenji

HASEBE Yasuaki

DBJ Capital Co., Ltd.

Website

Contact https://www.dbj-cap.jp/contact/

Website https://www.dbj-cap.jp/en/

DBJ Capital invests in wide range of industries as the venture capital arm of the Development Bank of Japan (DBJ). Life science sector is one of the focus areas of DBJ Capital. We have venture capitalists with extensive business and investment experience in this field and invest approximately 30% of our fund in this sector. As for hands-on activities, we focus on supporting fundraising, business management, recruitment, R&D, and business development, etc. We are unique in supporting alliances with large companies and domestic and international life science VCs by leveraging DBJ's client base. For more information, please visit our website.

DBJ Development Bank of Japan Group DBJ Capital Co., Ltd

Person in charge

MITSUGUCHI Hisashi

ISHIAI Hiroshi

YASUDA Yorinobu

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Outlines of Registered VCs

DCI Partners Co., Ltd.

Website

Contact dcip_info“AT”daiwa.co.jp

Website https://www.daiwa-inv.co.jp/dcip/en/

We have over 20 years' history of investing in biotech start-ups.
We are currently managing the largest size of the life science fund in Japan and playing a key role in supplying funds to promising start-ups.
We aim at increasing the value of our portfolios by providing various hands-on supports utilizing our team's expertise of clinical development, intellectual property and business development as well as our extensive network across academics, biotech and pharmaceutical industry primarily in Japan and Taiwan.
Beyond classical venture capital firms, we act as a platform to incubate seeds and create new start-ups that have great potential.

DCI Partners

Person in charge


YOKOTA Junichi


TANAKA Shoma


NIIMI Yuka

Eight Roads Ventures Japan

(Eight Roads Capital Advisors Hong Kong Limited)

Website

Contact admin“AT”eightroads.com

Website https://eightroads.com/en/

Global venture capital firm with deep analysis and understanding to science and technologies that can solve unmet medical needs and social problem. Stage agnostic investment from pre-foundation stage or seed stage to later growth stage. Leveraging global footprint as a fund and co-work with F-Prime Capital in US, a sister fund, Eight Roads Ventures Japan provides Japanese biotech startups with patient capital and hands-on support for global business expansion.

8∞ EIGHT ROADS™

Person in charge


KOMOTO Shinichiro


ASHIDA Hiroki

F-Prime Capital Partners

(Impresa Management LLC)

Website

Contact admin“AT”eightroads.com

Website https://fprimecapital.com/

Global venture capital firm with 20+ years experience in providing biotech startup with patient capital and hands-on support, based in US and cross-boarder to Japan, China, India and Europe. Deep analysis and understanding to science and technologies that can solve unmet medical needs and social problem. Stage agnostic investment from pre-foundation stage or seed stage, to later growth stage. Japan is one of focusing areas by co-working with the sister fund, Eight Roads Ventures Japan.

F/PRIME

Person in charge


KOMOTO Shinichiro


ASHIDA Hiroki


Robert Weisskoff


Brian Yordy

*Replace “AT” with “@”.

Fast Track Initiative, Inc.

Website

Contact https://us.fasttrackinitiative.com/contact-us/ | Website https://us.fasttrackinitiative.com/

Established in 2004, Fast Track Initiative (FTI) is a venture capital firm based in Tokyo, Japan and Boston, United States. Our mission since establishment has been to facilitate growth of innovative companies through investments that leads to life, vitality, and a healthier future. We turn to our depth of knowledge and experience in order to take on greater risks and challenges that lead to the discovery of novel sciences. We are always looking for new venture partners, corporate partners, and early stage startups.

FTI FAST TRACK INITIATIVE

Person in charge

KIRIYA Keita

JAFCO Group Co., Ltd.

Website

Contact https://jafco.co.jp/english/contact/ | Website https://jafco.co.jp/english/

We understand and deeply empathize with the aspirations of entrepreneurs to realize their businesses. We have executed investments of several hundred million yen, mainly in the seed/early stage, and have continued to execute investments after the initial round. The investment theme of the Investment Group for Academy & Life Science is to capture and dedicate the technological innovations that will change the world. The main areas of our investment are biotech, medical device, and health technology, which are essential to society, have high growth potential, and are expected to expand their markets, and we support the challenges of companies that aspire to innovative and creative management. We have been actively supporting biotech since the dawn of investment in Japan and have accumulated a great deal of knowledge and network. We concentrate our investments on next-generation innovative technologies and medical seeds that can be delivered to a large number of patients.

JAFCO

Person in charge

KITAZAWA Tomotake

KOBAYASHI Taira

MIURA Kengo

MIYAGAWA Yukari

ISHIMOTO Yuki

JIC Venture Growth Investments Co., Ltd.

Website

Contact info_lifescience“AT”j-vgi.co.jp | Website https://www.j-vgi.co.jp/en/

JIC Venture Growth Investments Co., Ltd. (JIC VGI), a venture capital arm of Japan Investment Corporation group (JIC), strategically drives Japanese innovation and global competitiveness. Focusing on diverse investment stages in life science, JIC VGI nurtures startups through a robust network encompassing venture capitals, pharmaceutical companies, and government agencies. We contribute to the strengthening of the venture ecosystem and the creation of new drugs originating in Japan.

JIC VENTURE GROWTH INVESTMENTS

Person in charge

URUNO Yoshiharu

SUZUKI Hanae

TSUZUKU Takuma

HIRUTA Koichi

*Replace “AT” with “@”.

Outlines of Registered VCs

Kyoto University Innovation Capital Co., Ltd.

Website

Contact ueno.hiroyuki“AT”kyoto-unicap.co.jp
https://www.kyoto-unicap.co.jp/en/contact/

Website https://www.kyoto-unicap.co.jp/en/

Kyoto University Innovation Capital Co., Ltd is the venture capital firm established as a wholly owned subsidiary of Kyoto University. We aim to contribute creating new industries that will lead the next generation by utilizing the research results of Kyoto University and Japanese national universities via investments. We've been supporting various biotech companies that promote the practical application from innovative university research results. In the “Drug Discovery Venture Ecosystem Enhancement Project”, we will support the research and development and business development of biotech companies to create new vaccine and new therapeutic option from the point of view of venture capital.

KYOTO-iCAP
KYOTO UNIVERSITY INNOVATION CAPITAL Co.,Ltd.

Person in charge


UENO Hiroyuki


YAGI Nobuhiro


KONO Osami

TSUJIMURA Tsuyoshi

YOKOO Koji

Mitsubishi UFJ Capital Co., Ltd.

Website

Contact ninteivc“AT”mucap.co.jp

Website https://www.mucap.co.jp/english/

Mitsubishi UFJ Capital invests in a wide range of industries as the venture capital of the Mitsubishi UFJ Financial Group. In the life science field, we have continuously established funds totaling ¥50 billion, including the Mitsubishi UFJ Life Science Fund IV (¥20 billion), since the first fund in February 2017. Our life science funds pursue the strategy of facilitating the creation of a drug discovery ecosystem in Japan. Specifically, besides follower investments in start-ups, we aim to support various processes from the nurturing of seeds for drug discovery to clinical development, by (1) drug discovery in academia: investing in start-ups that spun off from universities, (2) carveouts: investing in start-ups that were carved out from pharmaceuticals and specialize in specific technology or disease fields, and (3)open-innovation projects between academia and pharmaceuticals. Through these activities, we trust that we could contribute to advances in pharmaceutical development. We have several capitalists with pharmaceutical backgrounds, and we cover a wide range of drug discovery processes and disease areas in pharmaceuticals. In addition, we have concluded comprehensive agreements with specialized companies and organizations that can consult on intellectual property, non-clinical trials, pharmaceutical manufacturing, clinical development strategies, and medical needs, and have established a system that allows consultation before investment.

MUFG
Mitsubishi UFJ Capital

Person in charge


HASEGAWA Hiroyuki


SHINOZAKI Mikihiko


KAKIUCHI Akihito

SEKIYA Michiko

MIYOKO Nobuhiko

IZAWA Yosuke

KUBO Yuki

Miyako Capital Inc.

Website

Contact info"AT"miyakocapital.com

Website https://miyakocapital.com/en

We will invest in technology development-focused startup companies that utilize advanced intellectual assets from academia and research institutions, such as Kyoto University, across all stages from seed and early stages to middle and later stages, contributing to the SDGs. Additionally, we aim to foster the creation of next-generation leading industries and innovations through growth support activities such as industry-academia collaboration leading to the social implementation of technology.
We will continuously support by implementing effective industry-academia collaboration strategies tailored to the circumstances and needs of each company. Additionally, since all our members have extensive experience in VC investments in Japan, and overseas, including the United States, as well as in managing startup companies, we will provide comprehensive, hands-on support in practical aspects. This time, especially regarding drug discovery startups, we intend to actively support challenges from those who come from pharmaceutical companies and contribute to updating the drug discovery startup ecosystem.

MIYAKO CAPITAL

Person in charge


MISAWA Hiroyuki


OTANI Takayuki


TAMIYA Taiga

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MP Healthcare Venture Management, Inc. (MPH)

Website

Contact https://www.mp-healthcare.com/contact | Website https://www.mp-healthcare.com/

MP Healthcare Venture Management (MPH) is a Boston-based Lifesciences venture capital firm affiliated with Mitsubishi Tanabe Pharma Corporation (MTPC). MPH invests globally in early-stage companies developing innovative therapeutics and platform technologies. Our focus therapeutics areas are neurodegeneration, immunology, oncology, and rare diseases. Please see the detail of our current portfolio companies.

MP Healthcare Venture Management, Inc.

Person in charge

OZAWA Shota

Newton Biocapital Partners

Website

Contact https://newtonbiocapital.com/en/contact | Website https://newtonbiocapital.com/en/

Newton BioCapital ("NBC") is a venture capital fund with offices in Belgium and Japan investing in pre-clinical and clinical stage early stage companies in the life sciences sector in Europe and Japan. With a focus on reducing the burden on patients and society, NBC's strategy is to leverage innovation in the treatment of chronic diseases. The team members have a wealth of experience and a wide range of knowledge in the fields of chemistry, industry, and venture capital.

NEWTON BIOCAPITAL

Person in charge

SUZUKI Sadashi

WADA Michihiko

FUCHIKAMI Kinji

OSAKA University Venture Capital Co., Ltd.

Website

Contact info“AT”ouvc.co.jp | Website https://www.ouvc.co.jp/en/

Osaka University Venture Capital Co., Ltd. (OUVC) is a venture capital firm that supports ventures utilizing outstanding research outcomes not only from Osaka University but also from other national universities. ① Up until now, we have track records of investing primarily in the medical and pharmaceutical fields, and we have provided comprehensive support from startup to exit assistance. ② In recent times, we are focusing on finding CxO talent. We also leverage our status as a venture capital funded 100% by Osaka University and place emphasis on specialized hands-on support, including regulatory authority interactions, in collaboration with Medical Center for Translational Research Osaka University Hospital. We are ready to accept consultations from researchers at national universities who are not yet fully prepared for entrepreneurship, particularly focusing on national university settings. For more detailed information and contact details, please refer to our website.

OUVC

Person in charge

UOTANI Akira

UEHIRA Masahiro

*Replace “AT” with “@”.

Outlines of Registered VCs

Remiges Ventures, Inc. / RDiscovery, KK

Website

Contact info“AT”remigesventures.com

Website https://remigesventures.com/

Remiges is a venture capital operated by the investment team in Japan and the US and invests in and supports drug discovery startup companies. Our investments target all disease areas and all modalities. We invest in early-stage drug discovery ventures (Seed to Series A/B) that are developing advanced drugs. In addition, we create new ventures based on technologies from universities and other institutions. We typically act as lead investor and support comapnies through participation in the board of directors where we participate in a wide range of management activities including business strategy planning, external alliances and exit activities. Also, to increase company value after investment, we implement various measures such as strengthening the management team by hiring key management personnel, strengthen intellectual property by conducting detailed examinations, providing input in development strategy and clinical trial design, fundraising activities including inviting new investors, and introducing external advisors. We provide direct value-added services in drug development by assisting in accessing needed technologies, scientific expertise, and outsourced services to help ventures develop their business.

Person in charge

MATSUMOTO Kyoko

Saisei Ventures LLC

Website

Contact info“AT”saiseiventures.com

Website https://www.saiseiventures.com/

Saisei Ventures LLC is a leading venture capital firm focused on growing and harnessing the Japanese biotechnology ecosystem; a region rich in opportunities and potential. We create ventures that start from bold ideas and empower dynamic entrepreneurs by filling in technical, operational, or financial gaps. Our approach combines Western expertise and Japanese innovation to build globally competitive companies that will have the greatest impact on patient lives. We have offices in Japan and Boston, and our first fund is focused on fostering companies related to regenerative medicine, from fundamental technologies to groundbreaking cell and gene therapies originating in Japan.

Person in charge

SAITO Hikaru

Jonathan Yeh

Taiho Ventures, LLC

Website

Contact info"AT"taihoventures.com

Website https://taihoventures.com/

Taiho Ventures, LLC is a strategic corporate venture capital arm of Taiho Pharmaceutical Co., Ltd., a Japanese specialty pharma focusing on oncology and immune-related diseases. We actively invest in early-stage private companies in the areas of our focus and review a wide variety of modalities including biologics and small molecules. Taiho Ventures focuses on delivering cutting-edge technologies and therapies of startups to society not only by providing financial support but also by leveraging its experience in research and development and business management. The company also considers option type of investments and spin outs, in addition to the pure equity investments.

Person in charge

ASANUMA Sakae

ISHII Takaaki

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The University of Tokyo Edge Capital Partners Co., Ltd.

Website

Contact utec-kanri“AT”ut-ec.co.jp

Website https://www.ut-ec.co.jp/english/

Since its inception in April 2004, UTEC, in collaboration with entrepreneurs and researchers, has been investing in numerous startups that are tackling global challenges and advancing human progress. In the field of drug discovery, UTEC's investments span a diverse range of startups focusing on assets such as peptides, nucleic acids, cellular genes, and small molecules, as well as those equipped with advanced drug discovery platform technologies. These efforts are directed towards addressing areas of disease where new treatments are eagerly anticipated. Our members of highly specialized professionals in life sciences and drug discovery leverage our expertise and networks across various domains, including research and development, clinical trials, regulatory affairs, business development, and management and administration. We contribute significantly to the business expansion of drug discovery startups, both within Japan and internationally.

UTEC

Person in charge

USAMI Atsushi

SHIOHARA Azusa

UTokyo Innovation Platform Co., Ltd.

Website

Contact https://www.utokyo-ipc.co.jp/en/contact/

Website https://www.utokyo-ipc.co.jp/en/

UTokyo Innovation Platform Co., Ltd. (UTokyo-IPC) is a wholly-owned investment company by the University of Tokyo, actively investing in venture projects that utilize the achievements of the University of Tokyo and other universities. We provide hands-on support from experienced capitalists with a rich history of pharmaceutical investments, business development, and exit strategies in the United States and Japan. We welcome contact with bio-tech ventures engaged in innovative technology development, ranging from preclinical to Phase 2 clinical trials.

UTokyoIPC
Innovation Platform for The University of Tokyo

Person in charge

OHORI Makoto

BINGO Atsuhiro

*Replace “AT” with “@”.

Call for Proposals from Pharmaceutical Startups

Target of Call for Proposals

Field		Scale of Expenses Covered by Subsidy (Including indirect costs and Registered VC investment)	Subsidized Project Period
#1	Innovative technological development for development of infectious disease vaccines and therapeutic drugs.	[amount of money] (upper limit) 10 billion yen (Accept even if the upper limit is exceeded) AMED Subsidy covers up to 2/3 of the expenses.	Up to September 2031 (Set for each Adopted Project)
#2	Innovative technological development for development of pharmaceuticals etc. for diseases other than infectious diseases.		

- The applicant must have received, or be scheduled to receive in the future, investment from a Registered VC (must include the lead VC) in the amount of 1/3 or more of the expenses covered by the Subsidy.
- Pre-clinical study, Phase 1 clinical study, Phase 2 clinical study or Exploratory clinical study is covered.
- "Pharmaceuticals, etc." includes pharmaceuticals and regenerative medicine products.
- You must have filed a domestic or foreign patent application for the development candidate products. However, if you have not filed an application at the time of application for strategic reasons, please provide details of your strategy (development strategy, intellectual property strategy, business strategy, pharmaceutical strategy, etc.) in your proposal.
- If the final development candidate product has not been determined, proposals to conduct non-clinical studies to determine the final development candidate product are also accepted.
- If all Stage Gate Evaluations stipulated in the Subsidized Project Plan are passed, the Subsidized Project is up to September 2031.

Goals of this Program

- Completion of phase 2 clinical study or Exploratory clinical study (POC acquisition)
- If IPO & M&A is carried out during Subsidized Project Period, the Subsidized Project will be terminated in principle.

Evaluation Items

- Compatibility with the program's purpose
- Superiority and effectiveness of technology, etc.
- Development plans and goals
- Business plan
- Support plan by Registered VC

Frequency of call for Proposals

Several times a year.

＊Please check the latest Application Guidelines

List of Adopted Projects

(As of August 2024)

Subsidized Project	Business Operator	Page
Development of an innovative therapeutic agent for myotonic dystrophy type1 by a sequence-specific RNA binding protein targeting pathogenic CUG-repeat RNA	EditForce, Inc.	15
Development of RSV vaccine with novel antigen and adjuvant targeting TLR9 in pDC	Immunohelix Co., Ltd.	16
Development of ENDOPIN, a one-of-a-kind oral analgesic that activates the descending pain suppression pathway	BTB Therapeutics Co., Ltd.	17
Clinical proof of concept study of OZTx-556, a human iPS cell-derived cardiomyocyte, in a global clinical trial for patients with severe heart failure	Orizuru Therapeutics, Inc.	18
Obtaining POC in global Phase II clinical trial of a viral vector-based gene therapy	Restore Vision Inc.	19
Development of K_{ATP} channel inhibitor NTX-083 for Alzheimer's disease therapy	Neusignal Therapeutics, Inc.	20
Research and development of mitochondria replaced autologous T cells as pharmaceutical product for the treatment of cancer	Imel Therapeutics, Inc.	21
Development of hypoimmune iPS cell-derived cytotoxic T cell therapy for GPC3-positive solid cancer	Shinobi Therapeutics Co. Ltd.	22
Global development of corneal endothelial cell substitute from iPS cells (CLS001) and P1/P2 clinical trials	Cellusion Inc.	23
Development of a Novel Treatment for Refractory Metastatic Recurrent HER2-Negative Breast Cancer	Periotherapia Co., Ltd.	24
A novel cancer immunotherapy utilizing M2-like tumor-associated macrophage-selective nanoparticulate DDS encapsulated TLR agonist	United Immunity, Co., Ltd.	25
Development of ASCL-derived Platelet Like Cells (ASCL-PLC) as a regenerative medicine to treat intractable cutaneous ulcer	AdipoSeeds, Inc.	26
Development of SFG-02 for underactive bladder	Juro Sciences Inc.	27
Development of First-in-class oral lipid metabolism regulator PRD001 and POC obtained for lipid metabolism disorder.	PRD Therapeutics, Inc.	28
Development of a new LAT1 inhibitor for multiple sclerosis	J-Pharma Co., Ltd.	29
Research and Development of a Novel CAR-T Therapy, incorporating GITRL, on GD2 Positive Refractory Solid Tumors	T Cell Nouveau Inc.	30
Development of a new antibody drug to treat congenital tooth agenesis	Toregem BioPharma Co., Ltd.	31
Development of MGT-006, a Treatment Drug for Ulcerative Colitis	Metagen Therapeutics, Inc.	32
Development of a novel cell therapy using vascular endothelial stem cells for intractable skin ulcers associated with systemic sclerosis	Revascular Bio Co., Ltd.	33

Subsidized Project

Development of an innovative therapeutic agent for myotonic dystrophy type1 by a sequence-specific RNA binding protein targeting pathogenic CUG-repeat RNA

Business Operator

EditForce, Inc.

Principal Investigator
CSO Board of Directors
NAKANISHI Osamu, Ph.D.

Registered VC

Newton Biocapital Partners

Hands-on Representative
Advisor
Dr. WADA Michihiko

Overview

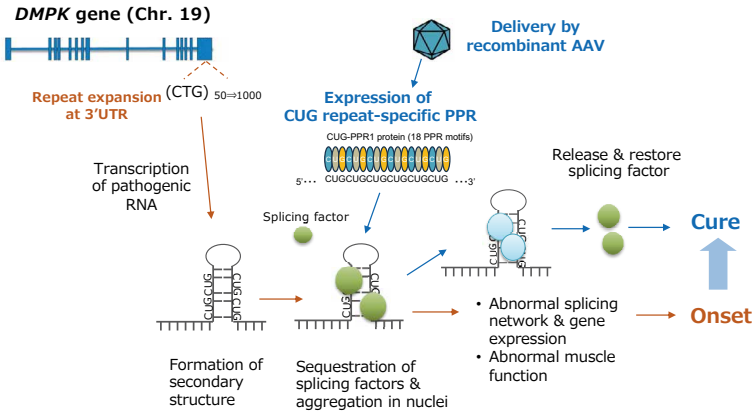
We have developed a unique technology to design artificial proteins by fusing a domain consisting of a plant-derived PPR (Pentatricopeptide Repeat) motif that can bind RNA in a sequence-specific manner with functional domains such as RNase and base editing enzymes.

The designed artificial proteins that can control RNAs that cause various diseases are under investigation for their therapeutic effects. The goal of this program is to develop a curative therapeutic agent by blocking the pathogenicity of CUG-repeat RNA that causes the intractable genetic disease myotonic dystrophy type 1 (DM1) by using our proprietary PPR technology.

Since the PPR technology can design proteins that bind to any RNA sequences, the success of this program is expected to provide a powerful platform technology in the future not only against disease-causing endogenous RNAs but also against exogenous RNAs of RNA viruses such as coronaviruses and dengue viruses.

Treatment of DM1 by PPR protein

- Myotonic dystrophy type 1 (DM1) is caused by abnormal splicing arising from sequestration of splicing factors essential for muscle function by expanded CUG repeat
- Delivery of a CUG repeat-specific PPR protein restores splicing factors and improves muscle function



Company Info

EditForce, Inc.

President and CEO
ONO Takashi, Ph.D.

We are researching and developing innovative gene-therapies, with our unique RNA editing technology ("PPR Platform Technology") utilizing PPR protein based on the study made by Kyushu University. PPR Platform Technology enables design of artificial proteins which will bind to targeted DNA/RNA sequences by applying PPR protein which is RNA combined protein in various plants with specific sequence and changing some amino acid of it. Off-target is the issue to overcome for DNA editing due to its irreversibility. With PPR Platform Technology, we can target specific genes at the RNA-level and control functions of the targeted genes. PPR Platform Technology has possibilities to take a different approach to gene controls which has not even been realized by the existing technologies. With the slogan of "New Tools Lead to a New World", our mission is to deliver safer and more reliable gene therapies to patients around the world suffering from genetic disorders as soon as possible.

Contact https://www.editforce.co.jp/en/contact/

Website https://www.editforce.co.jp/en/

Subsidized Project

Development of RSV vaccine with novel antigen and adjuvant targeting TLR9 in pDC

Business Operator

Immunohelix Co., Ltd.

Principal Investigator
Head of Research and Development
UNO Atsushi Ph.D

Registered VC

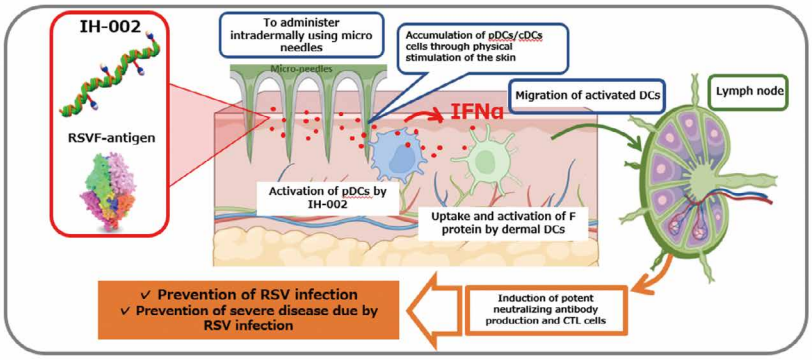
Remiges Ventures, Inc.

Hands-on Representative
Principal
NONOMURA Kazuhiko

Overview

The COVID-19 pandemic reminded us of the importance of vaccine development. Having solid vaccine research and related technologies in Japan is quite important from the perspective of national security and crisis management. Immunohelix proposes to develop a novel safe and effective RSV vaccine using a novel highly active adjuvant targeting plasmacytoid dendritic cells pDC (IH-002) and a novel RSV antigen in collaboration with Profs. Ueno, Hashiguchi, and Nakajima at Kyoto University. IH-002 is a complex composed of a patent-protected novel TLR9 agonist IH-002 ODN and β-glucan SPG, which forms a triple helix structure.

This complex is captured by the β-glucan receptor Dectin-1 expressed on pDCs and stimulates TLR9 in the cells effectively. This is the very unique biological profile of IH-002, which other DDS technology cannot achieve. In this project, the company plans to develop an intradermal RSV vaccine with microneedles in a simple mixture formulation of IH-002 to directly stimulate pDCs in the dermis. This is expected to produce high-affinity neutralizing antibodies by inducing a strong germinal center response in the lymph nodes through strong type I IFN production by pDCs. This is also expected to induce T cell responses such as cytotoxic T cells (CTL) and Th1 cells, which are important for antiviral activity, i.e., the establishment of robust acquired immunity. Through this project, the company aims to establish a manufacturing infrastructure that can produce GMP-grade IH-002. This will enable the company and Japan to supply it globally not only as an adjuvant for RSV vaccines but also as a universal adjuvant applicable to various infectious disease.



Company Info

Immunohelix Co., Ltd.

Representative derector
NAKAGAWA Atsuko

Immunohelix Co., Ltd. conducts research and development of pharmaceuticals, employing a drug delivery system technology grounded in the triple helix architecture of nucleic acids and sugar chains. The SPG (Schizophyllan) triple-helical technology allows drugs (e.g., nucleic acid drugs, medium and small molecules) to be bound to nucleic acids to form SPG complexes. The SPG complexes are selectively delivered via Dectin-1 (C-type lectin receptor), specifically expressed on the surface of antigen-presenting cells such as macrophages and dendritic cells among immune cells. This delivery technology has great potential for the creation of drugs in the therapeutic areas of the immune system, such as immunological diseases, cancer, organ transplantation, and infectious diseases, and our objective is to globally disseminate our delivery technology.

Contact https://www.napajen.com/en/contact/

Website https://www.napajen.com/en/

Subsidized Project

Development of ENDOPIN, a one-of-a-kind oral analgesic that activates the descending pain suppression pathway

Business Operator

BTB Therapeutics Co., Ltd.

Principal Investigator
Director
OGIKU Tsuyoshi Ph.D.

Registered VC

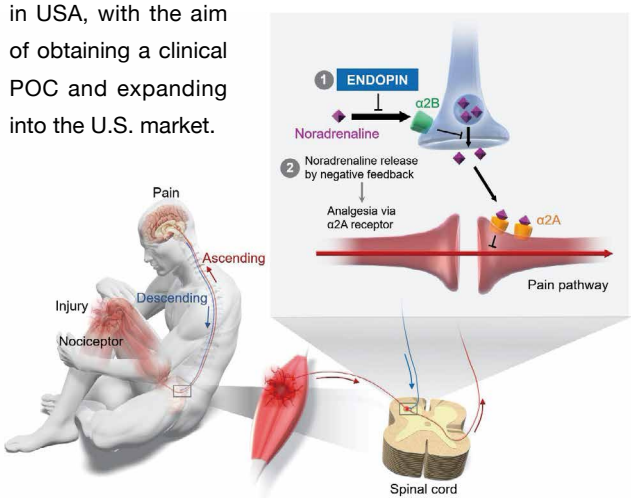
Kyoto University Innovation Capital Co., Ltd.

Hands-on Representative
Head of Investment Department I
YAGI Nobuhiro

Overview

ENDOPIN is a candidate compound for analgesics with a completely new mechanism of action, which was discovered by Hagiwara et al. at Kyoto University Graduate School of Medicine from their original compound library using an original idea based on a discovery with a novel assay method. Animals, including humans, increase noradrenaline secretion in times of crisis and activate the adrenergic receptor α 2A-dependent descending analgesics pathway to escape crisis without feeling pain. ENDOPIN, a selective inhibitor of the adrenergic receptor α2B, increases noradrenaline secretion into the cerebrospinal fluid through negative feedback caused by α2B inhibition, activating the descending pain suppression pathway, thereby producing analgesic effects. Based on this new hypothesis of action, ENDOPIN was tested in various pain models, including postoperative pain, inflammatory pain, and cancer pain. ENDOPIN showed strong analgesic effects comparable to those of morphine, but even at more than 100 times the effective dose, ENDOPIN showed no central nervous system effects, respiratory depression, or behavioral changes, as seen with morphine or other opioid analgesics, were observed.

Therefore, ENDOPIN has the potential to be a breakthrough analgesic to solve the opioid crisis, which has been a significant medical and social problem in the U.S. and Europe. In this project, we will conduct Phase II clinical trials in USA, with the aim of obtaining a clinical POC and expanding into the U.S. market.



Company Info

BTB Therapeutics Co., Ltd.

Chief Executive Officer
KIYOIZUMI Takashi
MD, PhD

BTB Therapeutics Co., Ltd. is a venture company established in June 2020 to develop drug discovery seeds originating from Kyoto University. Currently, in collaboration with Kyoto University Graduate School of Medicine, we are developing drugs for pain, next-generation cancer immunotherapy, and genetic disease RNA therapeutics. We are always aiming to obtain clinical POC as fast as possible, expand into the global market, and expand the range of indications.

Contact info“AT”btb-newdrug.co.jp
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Website https://www.btb-newdrug.co.jp/en/

Subsidized Project

Clinical proof of concept study of OZTx-556, a human iPS cell-derived cardiomyocyte, in a global clinical trial for patients with severe heart failure

Business Operator

Orizuru Therapeutics, Inc.

Principal Investigator
Head of iCM Therapy Business Unit
NISHIMOTO Tomoyuki, Ph.D.

Registered VC

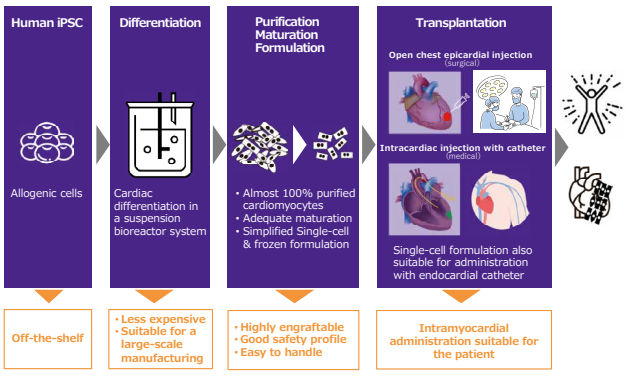
Kyoto University Innovation Capital Co., Ltd.

Hands-on Representative
Head of Investment Department II
UENO Hiroyuki, Ph.D.

Overview

Severe chronic heart failure (CHF) is a major cause of morbidity and mortality in the world. The prevalence of severe CHF is estimated at around 10 million in the EU, US, China, and Japan in 2036. About half of these patients are refractory to pharmacotherapy. For these patients, heart transplantation will be the last resort, and the Left Ventricular Assist Device (LVAD) has been developed as a circulation assist device mechanically for the purpose of bridge-to-transplantation. Recently LVAD has been also approved for use as a destination therapy in Japan in addition to the bridging use, yet it is not radical therapy compared to the replacement by functioned healthy cells, which can be expected "cure". In these situations, pluripotent stem cell-derived regenerative therapy is expected to be an innovative therapy for treatment-resistant severe heart failure patients. So far, we have developed new technologies to effectively produce highly engraftable and highly purified cardiomyocytes from human iPS cells. We demonstrated that these cells, named OZTx-556, engrafted both in rodent and monkey myocardial infarction models, and improved their cardiac functions. We plan to initiate a clinical trial in Japan to confirm the safety of OZTx-556 from FY24.
It is expected that several hundred million cells will need to be transplanted so that the transplanted cells to become viable and function in the heart. The production of such a large number of cells at low cost is a major challenge to overcome to expand the use of iPS cell-derived cardiomyocyte therapy to many patients.

Our method of cardiomyocyte differentiation is based on a suspension culture, rather than the monolayer culture used by many competitors, and is suitable for deployment to a low-cost large culture system. The project aims to establish a large-scale manufacturing method with a view to a commercial scale. In addition, the development of a catheter, which would be a less-invasive to patients, will be advanced to select the most advantageous administration method for patients compared to the current open chest administration, and together, we will conduct a global Ph1/2 study and obtain PoC, aiming for the progress to late-stage clinical development and early approval.



Company Info

Orizuru Therapeutics, Inc.

President,
Representative Director
and CEO
NONAKA Kenji.
M.D., Ph.D.

Orizuru Therapeutics, Inc., founded in April 2021, is steadfast in its dedication to bringing hope for better health through the infinite power of science. To deliver cell therapies to patients, the company promotes the wide use of cell therapy products and innovative iPSC-related technology through the following activities:

1. Development of regenerative medical products through cell transplantation
2. Support for drug discovery research and development of regenerative medicine research infrastructure using iPSC-related technology

For details, please refer to website.

Contact https://orizuru-therapeutics.com/en/contact/

Website https://orizuru-therapeutics.com/en/

Subsidized Project

Obtaining POC in global Phase II clinical trial of a viral vector-based gene therapy

Business Operator

Restore Vision Inc.

Principal Investigator
President & CEO
KATADA Yusaku, MD, Ph.D.

Registered VC

Remiges Ventures, Inc.

Hands-on Representative
Principal
NONOMURA Kazuhiko

Overview

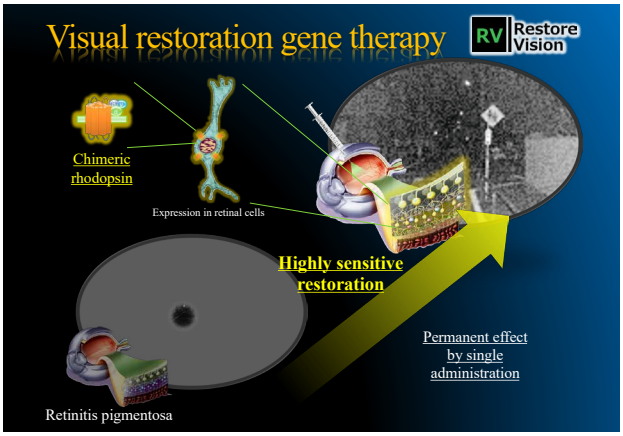
Retinitis pigmentosa (RP), a designated intractable and rare disease that is the second leading cause of blindness in Japan, along with other inherited retinal diseases and atrophic age-related macular degeneration (AMD), currently have no effective treatments and is necessitating urgent development globally. To address this unmet need, we are developing an innovative visual restoration gene therapy, or optogenetic therapy, using our proprietary light-sensor protein, Chimeric Rhodopsin (RV-001).

RP is a genetically diverse condition, with over 100 causative genes identified. This genetic heterogeneity complicates the development of mutation-specific treatments, requiring substantial resources and fragmenting potential market share. As RP eventually damages photoreceptor cells or retinal pigment epithelial cells regardless of the causative gene, gene-agnostic optogenetic therapies are in development to restore vision by expressing a light-sensor protein in cells that are not affected by RP. However, existing clinical trials utilize microbial rhodopsin, a light-sensor protein with limited sensitivity that is ineffective without goggles and still has a ways to go to visual restoration in low light conditions, which is imperative to improving the patients' QOL.

RV-001, our proposed gene therapy, utilizes adeno-associated virus vectors and is designed to have durable therapeutic effects with a single administration. Our core technology, Chimeric Rhodopsin stems from joint research between Nagoya Institute of Technology and Keio University. This high-sensitivity protein can function autonomously, surmounting the limitations of both animal and microbial rhodopsins, making it an ideal basis for visual restoration.

Patients with RP, for whom no treatment had been available, could restore their sight and their social engagement with this convenient, high-quality vision restoration treatment and potentially reduce social security expenses. Further, this treatment can be expanded to AMD patients who are also waiting for a cure.

This project will take full advantage of developing the drug in Japan, leveraging an established patient cohort network as well as a medical system and regulations favorable to launch the product as a first-in-class medication that can compete in the global market. This development plan builds upon these strengths, initially targeting specific patients in obtaining domestic P1/2a clinical trial data. Concurrently, we aim to expand our dataset to domestic P2b clinical trials that involve conditional and term-limited approvals, and international P2b clinical trials to move toward global approval.



Company Info

Restore Vision Inc.

President & CEO
KATADA Yusaku, MD, Ph.D.

We are a startup developing a visual restoration gene therapy using optogenetics technology for blindness caused by inherited retinal disorders. Founded based on promising results of joint research between Keio University School of Medicine and Nagoya Institute of Technology, Restore Vision's mission is to deliver gene therapy at light speed to patients waiting for effective treatment and, in doing so, contribute to the economy by marketing gene therapy technology rooted in academia.

Contact https://restore-vis.com/en/contact/

Website https://restore-vis.com/en/

Subsidized Project

Development of K_{ATP} channel inhibitor NTX-083 for Alzheimer's disease therapy

Business Operator

Neusignal Therapeutics, Inc.

Neusignal Therapeutics

Principal Investigator
Chief Development Officer
ARIMOTO Itaru, PhD.

Registered VC

Fast Track Initiative, Inc.

FTI FAST TRACK INITIATIVE

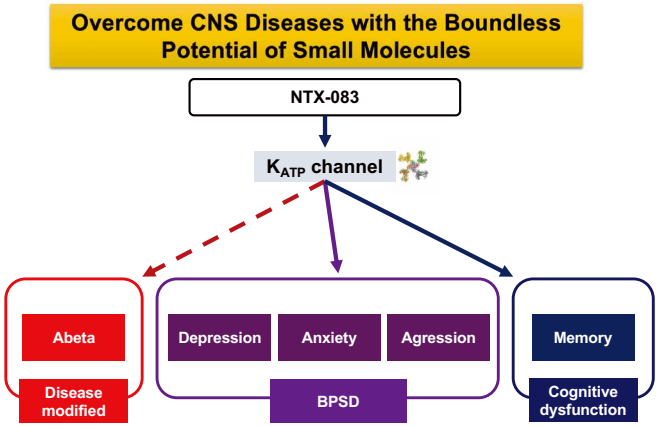
Hands-on Representative
Director
TAKEUCHI Makoto

Overview

To address one of the global challenges, Alzheimer's disease (AD), we aim to develop orally administered small molecule therapeutics with novel mechanisms of action. Approximately 70% of dementia patients are said to be AD. AD is a brain atrophy caused by neurodegeneration of the brain, and is characterized by a core symptom of cognitive dysfunction, and behavioral and psychological symptoms (depression, anxiety, aggression, etc.) that are peripheral symptoms. As the symptoms progress, the need for nursing care increases, and it is a serious disease that ultimately requires 24-hour assistance. The founder, Dr. Shigeki Moriguchi, associate professor at Tohoku University, and his colleagues discovered that the K_{ATP} channel, ATP-dependent potassium channels, play an important role in cognitive function and mental function. We confirmed NTX-083 selectively inhibits K_{ATP} channels and improves the core symptom of AD (cognitive dysfunction), as well as peripheral symptoms (depression, anxiety, and aggression) using animal disease models.

Furthermore, some results suggest disease-modifying effects of this compound, and we expect that NTX-083 would be a breakthrough treatment for AD that improves both core and peripheral symptoms.

In this project, we will develop NTX-083 globally by leveraging the strengths of NTX-083, and will clarify its unique mechanism of action through more detailed research.



Company Info

Neusignal Therapeutics, Inc.

Chief Executive Officer
YOSHIDA Yoshifumi, MBA

Neusignal Therapeutics, Inc. is developing drugs for the treatment of dementia, based on a new mode of action found by the founding scientists. Alzheimer's disease is considered to be one of the global challenges due to the ever-increasing number of patients owing to an aging population. We aim to make our first pipeline, NTX-083, to be an innovative therapeutic drug for Alzheimer's disease. NTX-083 has the potential to become a fundamental treatment for central nervous system disorders including Alzheimer's disease. Not to mention delivering NTX-083 to patients as soon as possible, we will strive to further expand our development pipeline based on new findings obtained through research and development.

Contact https://neusignal-tx.com/

Website https://neusignal-tx.com/

Subsidized Project

Research and development of mitochondria replaced autologous T cells as pharmaceutical product for the treatment of cancer

Business Operator

Imel Therapeutics, Inc.

イメル創薬株式会社

Principal Investigator
Chief Project Officer
KAMIYA Yuki

Registered VC

Remiges Ventures, Inc.

REMIGES VENTURES

Hands-on Representative
Managing Partner
INABA Taro

Overview

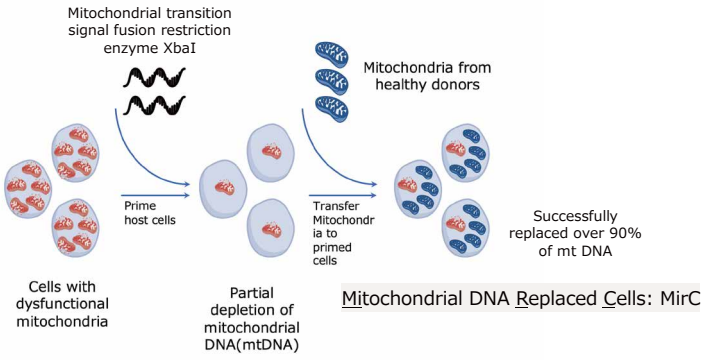
The discovery and development of immune checkpoint inhibitors and CAR-T cells have greatly advanced cancer immunotherapy. However, some patients do not respond to these therapies. One reason for this could be the exhaustion and senescence of immune cells, including T cells.

Initially, immune checkpoint inhibitors (ICIs) were thought to reactivate exhausted T cells. However, recent studies have shown that ICIs cannot reactivate fully exhausted T cells. Rather, these agents only act to increase the number of T cells before they become exhausted or to mobilize them to the tumor.

T-cell senescence has been attributed to age-related atrophy of the thymus gland and prolonged antigen stimulation, but recently it has also been reported that it is caused by the tumor environment. In senescent T cells, the ability to attack cancer is weakened, expression of co-stimulatory molecules CD27 and CD28 is decreased, and expression of inhibitory molecules such as PD-1 and KLRG-1 is increased. This would be a phenomenon distinct from T-cell exhaustion. Recent studies have shown that CD27 and CD28 are necessary for anti-PD-1 antibodies to be effective, so there is an urgent need to develop new therapies to eliminate T cell senescence and exhaustion for patients with inadequate response to ICIs.

Recently, it has been shown that abnormal mitochondrial function is involved in T cell exhaustion and aging. Mitochondrial function is impaired in T cells with advanced exhaustion, and the function to degrade and eliminate damaged mitochondria (mitophagy) is reduced in aged T cells. Therefore, it is believed that maintaining mitochondrial function is likely to prevent T cell exhaustion and senescence.

However, no treatment yet restores mitochondrial function and strengthens cancer immunity. Professor Gojo and his team were the first to discover that replacing T cell mitochondria may improve exhaustion and senescence. The clinical application of this technology is a unique and original feature of the applicant's technology. Successful development of this product will eliminate T-cell exhaustion and senescence in cancer therapy, dramatically increasing the therapeutic efficacy of existing drugs and extending the healthy life expectancy of patients.



Company Info

Imel Therapeutics, Inc.

Representative Director
INABA Taro

Imel Therapeutics, Inc. was established in Japan to develop innovative cell therapy based on the cellular mitochondrial DNA ("mtDNA") replacement technology discovered by Professor Satoshi Gojo and his colleagues at Kyoto Prefectural University of Medicine. We are currently developing autologous immune cell therapy with mitochondrial DNA replacement. Mitochondria, which are involved in intracellular energy production, decline in function with aging and other cellular stresses, causing immune cell dysfunction. Our technology can replace such dysfunctional mitochondria with healthy mitochondria, leading to the restoration of immune cell functions. This technology could provide new treatments in patients with cancer or other aging-related diseases for which there are currently no treatment options. In addition, this technology could be applied to improve existing therapies by normalizing exhausted immune cells.

Contact +81-3-5533-8589

Website https://imel-therapeutics.com/

Subsidized Project

Development of hypoimmune iPS cell-derived cytotoxic T cell therapy for GPC3-positive solid cancer

Business Operator

Shinobi Therapeutics Co. Ltd.

SHINOBI THERAPEUTICS

Principal Investigator

CEO, CTO

HITOSHI Yasumichi, MD, PhD

Registered VC

Impresa Management LLC

F/PRIME

Hands-on Representative

Partner

KOMOTO Shinichiro

Overview

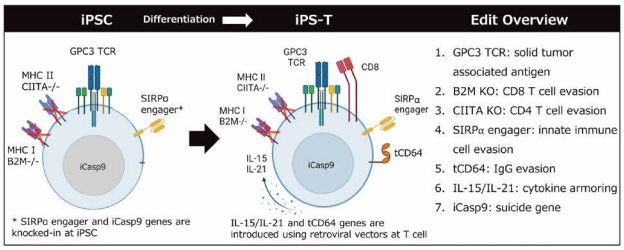
Engineered T cells, such as T cell receptor-transduced T cells (TCR-T) or chimeric antigen receptor-transduced T cells (CAR-T), have emerged as a promising next-generation adaptive immunotherapy. However, reproducible manufacturing with patients' T cells is still a bottleneck due to inconsistent qualities and insufficient quantities of cells from patients. In addition, further improvement of efficacy and repeated administration of the drug are important to realize a cure for solid tumors. Therefore, iPS cell-derived hypoimmune T cells are now being watched with special interest worldwide as an alternative source of cells. Shinobi Therapeutics Co. Ltd. (Shinobi JAPAN), a startup biotech company, has technology of generating hypoimmune iPS cell-derived T cells, and it is developing an hypoimmune iPS cell-derived cytotoxic T cell therapy product (NJA-001) that targets solid tumor expressing glypican 3 (GPC3).

GPC3 is a protein playing an important role in cell proliferation and embryonic tissue formation, and is highly expressed in malignant cells such as hepatocellular carcinoma (HCC), colorectal cancer (CRC), and lung cancer (LC). Adult normal organs/tissues do not express GPC3, thus GPC3 is regarded as a promising target for cancer immunotherapy. In Japan, about 40 thousand, 160 thousand, 130 thousand people, are diagnosed as HCC, CRC and LC each year, respectively. For the late-stage patients with those cancers have poor prognosis, therefore, more effective therapy is desired.

NJA-001 is hypoimmune iPS cell-derived CD8$\alpha\beta$ cytotoxic T lymphocytes (CTL), which have effective antigen recognition via GPC3-specific TCR and potent cytotoxic activity. The cells are manufactured through differentiation from hypoimmune iPS cells that were transduced with TCR gene specific to HLA A*24:02-restrictive GPC3 peptide. The following features of NJA-001 suggest that it could be an alternative therapeutic option for late-stage HCC patients who are resistant to standard therapies.

- Very potent antigen-specific cytotoxicity mechanism
- Complete evasion of rejection by any of the patient's own immune cells
- An off-the-shelf product produced through all feeder free culture process, ready for immediate administration once patients enter the treatment

The production process of iPS cells with immune rejection evasion ability transfected with the GPC3 antigen-specific TCR gene, which is the starting material for NJA-001, under GMP is the finalization of the process. Shinobi JAPAN will manufacture the clinical product at CiRA foundation, and perform phase I and II clinical trials at Kyoto Innovation Center for Next Generation Clinical Trials and iPS Cell Therapy (Ki-CONNECT), Kyoto university. All the clinical development centers at Kyoto University.



Company Info

Shinobi Therapeutics Co. Ltd.

CEO, CTO

HITOSHI Yasumichi, MD, PhD

Shinobi Therapeutics is a new iPS cell therapycompany formed by the merger of Japan's Thyas and the USA's EvadeBiotechnology. Professor Shin Kaneko of Kyoto University, a leader infeeder-free iPS-T cell development, and Professor Tobias Deuse of UCSF, who hasdeveloped innovative hypo-immune mechanisms and engineering strategies, formthe foundation of the company. These combined cutting-edge technologiespromise transformative off-the-shelf cell therapies.

Contact info"AT"shinobitx.com

＊Replace "AT" with "@".

Website https://www.shinobitx.com/

Subsidized Project

Global development of corneal endothelial cell substitute from iPS cells (CLS001) and P1/P2 clinical trials

Business Operator

Cellusion Inc.

Principal Investigator
Founder & CEO
HATOU Shin, M.D., PH.D.

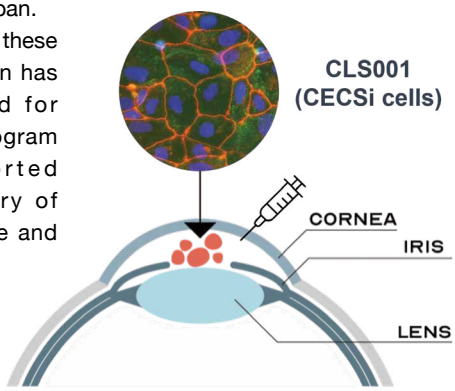
Registered VC

The University of Tokyo Edge Capital Partners Co., Ltd.

Hands-on Representative
Partner
KOBAYASHI Hiroaki, M.D.

Overview

There are over 12.7 million patients around the world waiting for keratoplasty (corneal transplant), while only 180,000 receive surgery annually.
Over half of the indications for keratoplasty is due to cornea endothelial dysfunction (bullous keratopathy). To address the unmet medical needs, Cellusion Inc. in collaboration with the Department of Ophthalmology at Keio University School of Medicine, have developed a new cell therapy using a corneal endothelial substitute cells from allogenic iPS cells (CLS001) for the treatment of bullous keratopathy.
The first patient of cell transplant was performed at Keio University Hospital in October 2022. There have been no adverse events, and postoperative outcomes including visual acuity and corneal thickness are improving.
We are preparing for phase 1/2a clinical trial. For example, we have already started technology transfer to a CDMO, Nikon Cell Innovation Co., LTD. In addition, a capital and business alliance has been concluded with TOHO HOLDINGS CO., LTD., one of leading pharmaceutical wholesaler groups in Japan.
In this project, our goals are to obtain POC through P1/P2 clinical trials in Japan and to initiate U.S. development and P1 clinical trials. In Japan, we will prepare and implement manufacturing for clinical trials, conducting non-clinical studies and P1/P2 clinical trials. In the U.S., we aim to negotiate with the FDA to start P1 clinical trials.
If the bullous keratopathy treatment with CLS001 is put into practical use, it will be possible to treat patients worldwide with corneal blindness using regenerative medical products derived from iPS cells originating in Japan.
In recognition of these efforts, Cellusion has been selected for "J-Startup" program to be supported by the Ministry of Economy, Trade and Industry in 2023.



Allogeneic Cell Transplant

Company Info

Cellusion Inc.

Founder & CEO
HATOU Shin, M.D., PH.D.

Cellusion Inc. is a regenerative medicine startup from Keio University School of Medicine that aims to develop a new regenerative medicine for the cornea using iPS cells.
Due to the current worldwide shortage of donors, many patients with corneal diseases are waiting for transplants. To solve this problem, Cellusion is developing a regenerative medicine for the treatment of bullous keratopathy, which accounts for more than half of all corneal transplant cases. By developing a surgical method that reduces the burden on patients by mass culturing of corneal endothelial cells substitute from iPS cells using proprietary technology and transplanting these cells by injection, we aim to solve the problems of corneal transplantation associated with donor shortage etc. and contribute to corneal patients worldwide.

Contact https://cellusion.jp/en/#contact

Website https://cellusion.jp/en/

Subsidized Project

Development of a Novel Treatment for Refractory Metastatic Recurrent HER2-Negative Breast Cancer

Business Operator

Periotherapia Co., Ltd.

Principal Investigator
Chief Executive Officer
TOCHIHARA Yosuke

Registered VC

OSAKA University Venture Capital Co., Ltd.

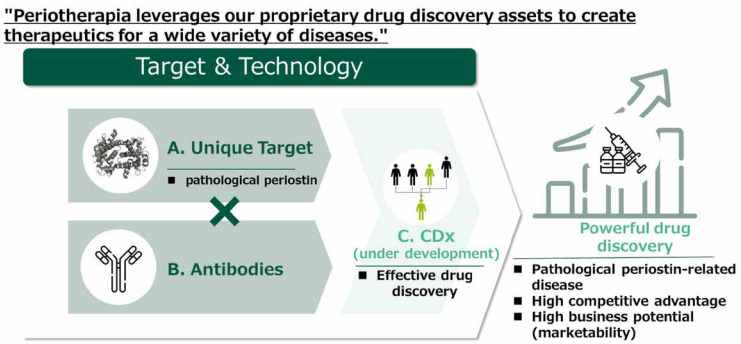
Hands-on Representative
Director Investment Division
UOTANI Akira

Overview

Periotherapia Co., Ltd. is a drug discovery venture originating from Osaka University and developing antibody drugs for intractable diseases. We have competitive advantage and high business potential through our drug discovery assets that combine multiple therapeutic antibodies and diagnostic development. As its first pipeline, we are ready to start clinical trials in Japan for breast cancer, especially for refractory metastatic recurrent HER2-negative breast cancer. In the future, we aim to grow into a leading global speciality pharmaceutical company.

The prognosis of breast cancer has improved dramatically due in part to advances in targeted therapies. However, triple-negative breast cancer, a type of HER2-negative breast cancer, has an extremely poor prognosis and is a global problem because it lacks therapeutic target and frequently occurs in the AYA generation. We have discovered "periostin" a factor that induces resistance to anti-cancer drugs in various types of cancer and have identified a periostin splicing variant that is specifically expressed in and contributes to pathological conditions. The antibodies with high safety profile and tumor specificity has been developed and can be used to treat multiple diseases. We also work on the co-development of antibody-drug conjugates, which has the potential to grow into a global spciality pharmaceutical company in the future.

We will conduct clinical trials in Japan and the U.S. and detailed mechanistic studies to achieve early out-licensing and marketing of the antibodies. The prognosis of metastatic recurrent HER2-negative breast cancer is extremely poor and a new treatment that improves the prognosis will bring good news to AYA women around the world.



Company Info

Periotherapia Co., Ltd.

Chief Executive Officer
TOCHIHARA Yosuke

Periotherapia Co., Ltd. is a drug discovery venture originating from Osaka University that was established in October 2017 by Director Yoshiaki Taniyama. Periostin, an extracellular matrix protein involved in heart valve formation and wound healing, has pathological periostin variants (hereinafter referred to as "pathological periostin") that are associated with various intractable diseases such as breast cancer, diabetic retinopathy, and myocardial infarction. We are developing medicines to treat these diseases.

In particular, we focused on the strong involvement of pathological periostin in triple-negative breast cancer (TNBC), which is difficult to treat among breast cancers, and selected metastatic and recurrent HER2-negative breast cancer, including TNBC, as the first indication for antibody drugs We are proceeding with the development of Because TNBC is more likely to affect young women and is highly malignant with a 5-year survival rate of less than 50%, there is a need for the early development of new therapeutic agents.

Contact https://periotherapia.co.jp/contact.php

Website https://periotherapia.co.jp/

Subsidized Project

A novel cancer immunotherapy utilizing M2-like tumor-associated macrophage-selective nanoparticulate DDS encapsulated TLR agonist

Business Operator

United Immunity, Co., Ltd.

UNITED IMMUNITY

Principal Investigator
Chairman, Head of R&D
HARADA Naozumi

Registered VC

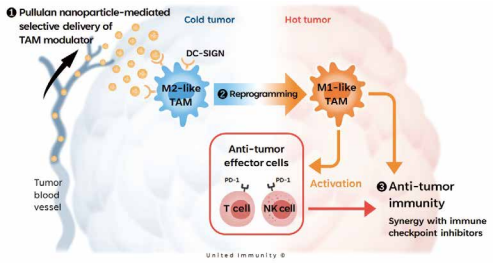
UTEC

The University of Tokyo Edge Capital Partners Co., Ltd.

Hands-on Representative
Partner and Board Director
USAMI Atsushi

Overview

- The majority of cancer patients are resistant to existing immunotherapies. One of the main causes of tumor immune resistance is immunosuppressive M2-like tumor-associated macrophages (TAMs) in the tumor microenvironment. Pharmacological reprogramming them into immunostimulatory M1-like TAMs is attracting worldwide attention as a novel therapeutic strategy to break tumor immune resistance. Therefore, various M2-like TAM-reprogramming drug candidates including agonists for TLRs and STING have been evaluated in the clinical setting; however, most of these drugs failed to show clinical safety and efficacy due to the lack of M2-like TAM specificity.
- The applicant recently discovered that pullulan nanogel, a unique hydrogel nanoparticle composed of cholesteryl pullulan, functions as a drug delivery system (DDS) that selectively accumulates in M2-like TAMs after systemic administration in mouse tumor models. The applicant also identified the polysaccharide receptor protein DC-SIGN, which is specifically expressed on M2-like TAMs, as a physiological receptor for pullulan nanogel DDS. In human solid tumors with poor prognosis or high stage, M2-like TAMs are reported to express DC-SIGN frequently. In contrast, expression of DC-SIGN in normal tissues is very limited. Therefore, DC-SIGN is a suitable target for selective drug delivery to M2-like TAMs in advanced tumors, and the applicant's pullulan nanogel DDS is ideal for this purpose.
- The applicant has generated UI-102, a new pullulan nanogel formulation loaded with a TLR agonist for systemic administration with the aim of creating a new drug with less side effects to reverse tumor immune suppression by modulating M2-like TAM functions. The pharmacological activity of UI-102 was confirmed in mouse tumor models and in vitro human macrophages. Preliminary safety evaluation in animals shows toxicity of the TLR agonist is greatly mitigated by using pullulan nanogel DDS. A GMP-compliant drug manufacturing process is being developed.
- In this project, the applicant will first accomplish IND-enabling preclinical studies, manufacturing of the clinical test materials, and preparation for clinical studies. FIH Ph1 studies in patients with advanced cancer will begin in 2025 for clinical safety evaluation. Ph2 studies will follow to establish a clinical POC by 2030.
- UI-102 will offer a new therapeutic option to majority of solid tumor patients who is refractory to standard therapies.



Company Info

United Immunity, Co., Ltd.

President
KISHIDA Masato, Ph.D, MBA

UnitedImmunity is a biotech company aiming to unite the power of immunity and nanoparticle to change the future of patients.
Our proprietary “Myeloid Targeting Platform” enable us to deliver variety of modality such as mRNA/small molecule to macrophages and dendritic cells . We develop our own pipeline as immune oncology program, but our platform technology is applicable to infectious / autoimmune / fibrosis disease. We run platform collaborations with pharmaceutical companies in those therapeutic areas.
We wish to be a leading role model of deep tech in Japan by achieving launch of block buster drug as well as making successful partnering, and change ecosystem as a representative role model.

Contact https://unitedimmunity.co.jp/eng/contact

Website https://unitedimmunity.co.jp/eng/

Subsidized Project

Development of ASCL-derived Platelet Like Cells (ASCL-PLC) as a regenerative medicine to treat intractable cutaneous ulcer

Business Operator

AdipoSeeds, Inc.

脂肪から血小板をつくり、あたらしい血液の流れを創る。

AdipoSeeds

Principal Investigator

CSO

MATSUBARA Yumiko, PhD

Registered VC

DCI Partners Co., Ltd.

DCI Partners

Hands-on Representative

Director

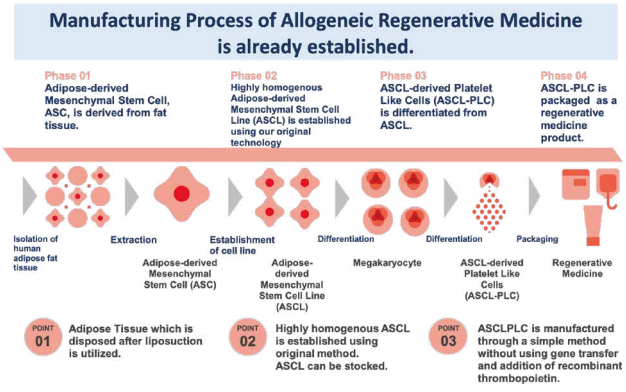
HAYAKAWA Norihide

Overview

The mechanism by which platelets are produced from adipose-derived mesenchymal stem cells developed by AdipoSeeds is that mesenchymal stem cells contain the transcription factor p45NF-E2 and thrombopoietin which are the determinant of differentiation to platelets. Although the expression of these factors is slight during the maintenance culture of mesenchymal stem cells, the expression increases when cultured with megakaryocyte-platelet differentiation-inducing medium containing transferrin. Through the research to clarify this mechanism, we found that there was no need for genetic introduction or the addition of recombinant protein when manufacturing platelets. Together with the availability of raw materials (mainly aspirated fat tissue enforced for beauty purposes) and the establishment of ASCL (Adipose-derived Mesenchymal Stem Cell Line) using our proprietary technology, it became clear that the systematic production of platelets would be available.

We believe that ASCL-PLC (ASCL derived platelet-like cell) can contribute to the therapeutic areas of platelet transfusion and tissue repair because they have the properties of both blood stem cell-derived platelets and Mesenchymal Stem Cell.

In this project, we will develop an allogeneic regenerative medicine product for the treatment of intractable cutaneous ulcer . As a background, the treatment of intractable cutaneous ulcer requires a long period of time, and the recurrence rate is also high. Thus, a new treatment approach that promotes ulcer healing is desirable. We aim to complete exploratory trials and establish a POC by fiscal 2027.



Company Info

AdipoSeeds, Inc.

CEO＆CFO

FUWA Junji

AdipoSeeds, Inc. was established in July 2016 to develop an allogeneic regenerative medicine using ASCL-derived Platelet Like Cells (ASCL-PLC) which is multifunctional platelets and created based on the novel research result by Yumiko Matsubara, visiting professor at Institute for integrated Sports Medicine , School of Medicine, Keio University.

Our corporate mission is “Making Platelets from Fat Tissue and Inventing New Blood Supply System” and we aim to realize a stable supply of platelet products with safety. Currently, we are engaged in development for the treatment of intractable cutaneous ulcer and for medical applications as a platelet for transfusion.

Contact

+81-3-6822-0325

info“AT”adiposeeds.co.jp

＊Replace “AT” with “@”.

Website https://www.adiposeeds.co.jp/en/

Subsidized Project

Development of SFG-02 for underactive bladder

Business Operator

Juro Sciences Inc.

Principal Investigator
Board member, Chief Scientific Officer
TANAKA Akira, PhD

Registered VC

Miyako Capital Inc.

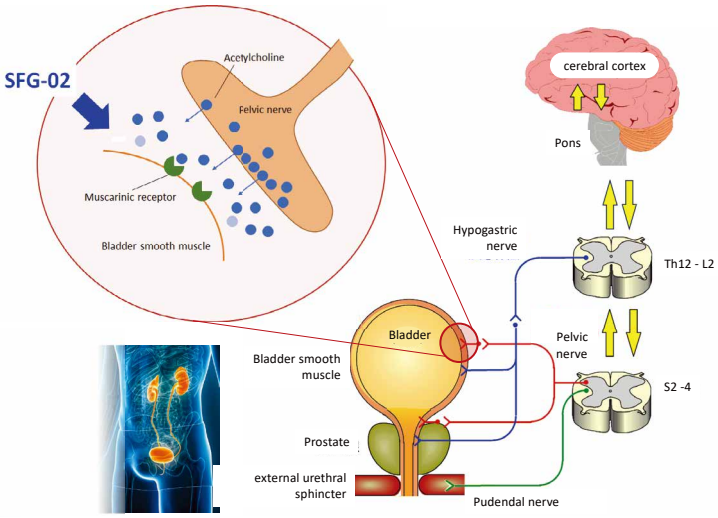
Hands-on Representative
Partner
MISAWA Hiroyuki

Overview

Underactive bladder (UAB) is a symptom complex caused by a decrease in the contractility of detrusor due to aging or central or peripheral neuropathy. Symptoms include reduced sensation of bladder fullness, decreased voiding volume, decreased stream, straining, frequent urination, urinary incontinence, urinary retention, and frequent urinary tract infections, which can significantly reduce patients' quality of life. The number of potential patients is large, while the lack of effective treatments has created a huge unmet medical need.

SFG-02 is an innovative novel small molecule enzyme inhibitor in development for the treatment of UAB. Multiple preclinical studies have demonstrated high selectivity to the molecular target and optimal efficacy in animal models of UAB. Non-clinical toxicity, safety and pharmacokinetic study results to date support an IND application and initiation of a Phase I study in healthy adults.

After confirming the pharmacokinetics and safety and tolerability of SFG-02 in the Phase I study, we plan to conduct a global Phase IIa study in UAB. We expect that SFG-02 will be the first truly effective treatment for the many patients worldwide with UAB who have negatively impacted quality of life.



Company Info

Juro Sciences Inc.

Representative Director, CEO
NAGABUKURO Hiroshi, PhD

Juro Sciences Inc is a biopharmaceutical company founded in 2021 to provide innovative solutions for underactive bladder (UAB). The pipeline asset SFG-02 leverages the Company's extensive expertise in drug discovery and combines a novel drug delivery system with targeted therapeutic mechanisms to minimize side effects and maximize efficacy. Our strong commitment to quality R&D, regulatory compliance, and external strategic partnerships will keep us at the forefront of the pursuit of new UAB therapies.

Contact https://www.sfgsci.com/en/contact/

Website https://www.sfgsci.com/en/juro/

Subsidized Project

Development of First-in-class oral lipid metabolism regulator PRD001 and POC obtained for lipid metabolism disorder.

Business Operator

PRD Therapeutics, Inc.

Principal Investigator
Representative Director
HOSODA Kanji, Ph.D

Registered VC

JAFCO Group Co., Ltd.

Hands-on Representative
Principal
KOBAYASHI Taira, Ph.D

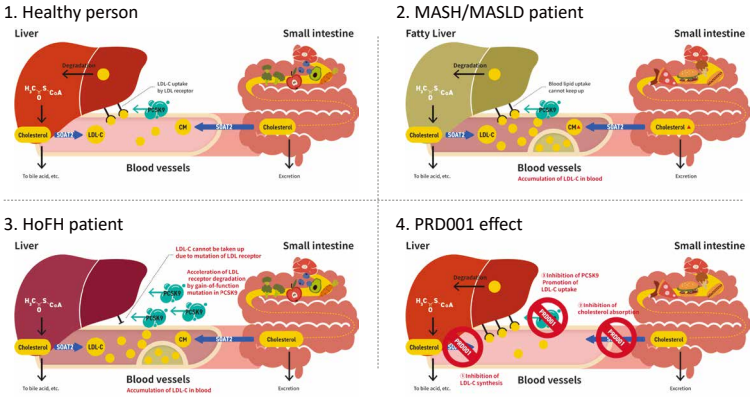
Overview

This project aims to obtain clinical proof of concept for PRD001, a new lipid metabolism regulator. PRD001 can be developed for either homozygous familial hypercholesterolemia (HoFH) or metabolic dysfunction-associated steatohepatitis (MASH)/metabolic dysfunction associated fatty liver disease (MASLD).

HoFH is a rare-hereditary disease caused by a mutation in the LDL receptor-related genes. HoFH is often resistant to existing drugs, and new drugs are strongly required. In addition, although there are many patients with MASH/MASLD around the world, but approved drug has only recently been released, and the development of new drugs is strongly required. MASH/MASLD is fatty liver disease caused by metabolic dysfunction, diabetes, obesity, etc.

PRD001 is the world's first selective inhibitor of SOAT2, and has the potential to become a new, innovative therapeutic drug for HoFH that lowers bad cholesterol and inhibits arteriosclerosis. It may also be a therapeutic drug with a new mechanism for improving lipid metabolism disorders and impaired glucose tolerance and inhibiting the progression of fatty liver in MASH/MASLD. Excellent efficacy and safety have already been confirmed in animal tests.

In this project, we will manufacture investigational drugs and conduct clinical trials to verify whether PRD001 can become a new therapeutic drug for HoFH and MASH/MASLD.



Company Info

PRD Therapeutics, Inc.

Representative Director
HOSODA Kanji, Ph.D

PRD Therapeutics is a drug discovery startup developing novel lipid metabolism regulators.
We are developing oral first-in-class new drugs with PRD compounds, the world's first and only SOAT2 selective inhibitors.
We are developing not only for patients with rare diseases but also for patients with lifestyle diseases related to lipid disorder.
By developing new oral drugs, which is more convenient and less burdensome for patients, we will bring new drugs and smiles to patients and their families around the world.

Contact info“AT”prdtherapeutics.com
＊Replace “AT” with “@”.

Website https://prdtherapeutics.com/en/

Subsidized Project

Development of a new LAT1 inhibitor for multiple sclerosis

Business Operator

J-Pharma Co., Ltd.

J-Pharma

Principal Investigator
Director, Regulatory Affairs Department
YOSHIDA Tsuyoshi

Registered VC

Eight Roads Capital Advisors Hong Kong Limited

8∞ EIGHT ROADS™

Hands-on Representative
Partner
KOMOTO Shinichiro, Ph.D.

Overview

Multiple sclerosis (MS) is the most common chronic inflammatory demyelinating neurological disease in young adults. According to the 2020 Patient Survey by the Ministry of Health, Labor and Welfare, the number of patients with multiple sclerosis is estimated to be 7,000 males and 11,000 females, for a total of 18,000 patients.

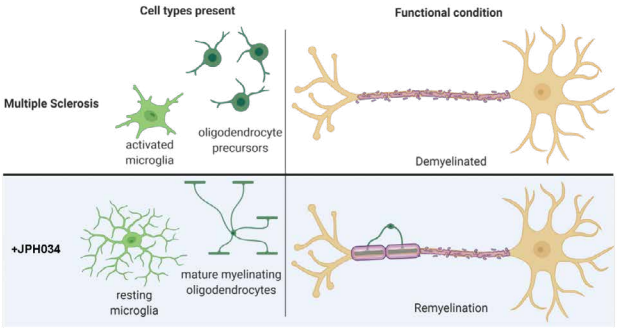
MS is designated as an intractable disease under the "Act on Medical Care and Treatment for Persons with Specified Intractable Diseases." It develops as relapsing-remitting disease (RRMS) and progresses to secondary progressive MS (SPMS), which is marked by the development of permanent neurological deficits and progressive clinical disability. Approximately 10% to 15% of patients also have primary progressive MS (PPMS), which progresses gradually from onset to permanent neuropathy without relapsing-remitting disease. Medications for the treatment of MS, such as oral fumarates and sphingosine-1-phosphate modulators, have been approved as disease-modifying therapies. However, their efficacy relatively diminishes as the disease progresses.

MS, which is characterized by chronic central local inflammation, is also defined as smoldering MS, and is thought to be caused by metabolic reprogramming of immune cells in the affected local tissues.

Amino acids and their metabolites have been shown to be involved in the activation of microglia, which are the main components of such chronic local inflammation, and it has been suggested that regulating these components promotes remyelination.

Based on the idea that LAT1 is involved in the metabolic reprogramming process of activated microglial cells, where the utilization of amino acids from the glycolytic system is enhanced, similar to cancer, we conducted joint research with Georgetown University in the U.S. We found that in a mouse model of demyelination, LAT1 is specifically highly expressed in activated microglia that accumulate in demyelinated lesions.

JPH034 (formerly known as OKY-034), a LAT1 non-competitive inhibitor discovered by Osaka University, inhibits microglial activation and promotes the differentiation of oligodendrocytes, which is an indicator of remyelination. With the improvement of MRI technology, it is possible to monitor the progression of smoldering MS pathology by visualizing the iron deposition in microglia at the MS focal lesion margin as paramagnetic Rim lesions. We will utilize the latest MRI and PET technologies to determine the efficacy of JPH034 as a treatment for progressive MS, a disease with a high unmet need.



Company Info

J-Pharma Co., Ltd.

Representative Director
and President & CEO
YOSHITAKE Masuhiro

Founded in 2005, J-Pharma is a global drug discovery venture with a corporate philosophy of contributing to people around the world to maintain good health and hope through the development of innovative new drugs that address unmet medical needs by pursuing new possibilities for SLC transporters.

J-Pharma is focusing on LAT1 (L-type amino acid transporter 1), discovered by its founder, Prof. Hitoshi Endo, and is developing LAT1 inhibitors that address the needs of patients with cancer and autoimmune diseases that cannot be treated by existing drugs. Nanvuranlat attracted the attention of researchers around the world after an oral presentation at the American Society of Clinical Oncology (ASCO) of its clinical efficacy in a Phase II study of 106 patients with advanced biliary tract cancer. We are currently preparing for the start of a global Phase III study in biliary tract cancer next spring. We are also preparing for global clinical trials for a wide range of diseases in collaboration with various research institutions. In addition, we have started drug discovery research on candidate compounds for SLC transporter inhibitors other than LAT1.

Contact info“AT”j-pharma.com
＊Replace “AT” with “@”.

Website https://www.j-pharma.com/en/

Subsidized Project

Research and Development of a Novel CAR-T Therapy, incorporating GITRL, on GD2 Positive Refractory Solid Tumors

Business Operator

T Cell Nouveau Inc.

Principal Investigator
CEO
TAKESAKO Kazuto, Ph.D.

Registered VC

DBJ Capital Co., Ltd.

DBJ Development Bank of Japan Group DBJ Capital Co.,Ltd

Hands-on Representative
Senior Investment Manager
MITSUGUCHI Hisashi

Overview

CAR-T therapy for solid tumors were not successful due to the various reasons. This project aims to develop a novel CAR-T therapy against refractory solid tumor.

This CAR-T is targeting GD2 ganglioside, one of the glycolipids, expressed on the surface of various tumor types, and nonclinical studies have been investigated. The features are as follows:

1) The scFV of highly specific anti-GD2 antibody is applied as the external domain, enabling to increase the specificity against tumors while eliminating cross-reactions with normal tissues.

2) The CAR-T has a novel gene structure, installing GITRL (Glucocorticoid-induced TNF receptor related protein ligand) as co-stimulating factor, enhancing anti-tumor effect.

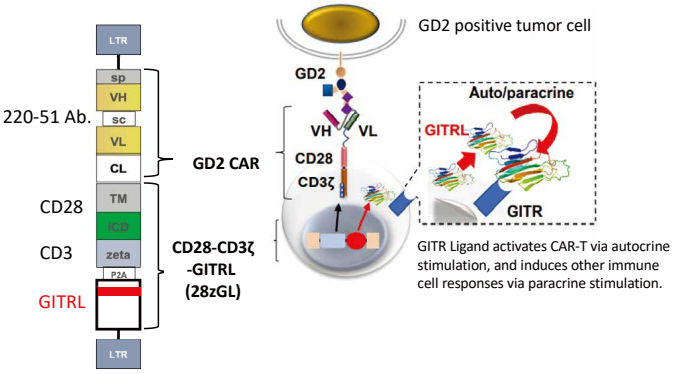
Furthermore, in order to manufacture GD2 GITRL CAR, the completely closed automatic cell manufacturing system will be hired, which we can expect cost reduction due to the following reasons:

1) Each step check is not necessary.

2) Large amount investment for manufacturing facility is not necessary.

For pediatric patients, the blood draw amount will be limited. Therefore, we will establish CAR-T manufacturing process using both peripheral blood and apheresis blood as a starting material, followed by the consultation with PMDA, then we will conduct the clinical trial for refractory neuroblastoma.

Next Generation CAR Internal Signal Domain
In addition to CD28 signal, GITR Ligand is constantly secreted.



Company Info

T Cell Nouveau Inc.

CEO
TAKESAKO Kazuto, Ph.D.

T Cell Nouveau is a bio-venture company, which develops original gene-modified immune cells as regenerative medicine. Especially, our intention is to treat solid tumors using our originally developed gene-transduced T cells, installing target tumor antigen and immuno-activation genes. T Cell Nouveau strongly believes that our CAR/TCR-T cells transduced therapeutical gene is an innovational technology and a breakthrough of the limit with current CAR-T or TCR-T cell therapies, aiming the solid tumors with which it does not respond. Our patented technologies of antibodies applied for CAR-T cells are highly specific against tumors, and our target antigens are glycolipid antigen GD2 and peptide-MHC complex antigen (MAGE-A4 or PRAME). Furthermore, T Cell Nouveau patented technology, GITR Ligand, enables to support activating, maintaining, and sustaining T cell function under immunosuppressive tumor microenvironment. We proudly deliver these unique technologies to the clinical sites worldwide.

Contact https://www.tcellnouveau.com/en/contact

Website https://www.tcellnouveau.com/en

Subsidized Project

Development of a new antibody drug to treat congenital tooth agenesis

Business Operator

Toregem BioPharma Co., Ltd.

Principal Investigator
CTO, Director
TAKAHASHI Katsu D.D.S., Ph.D.

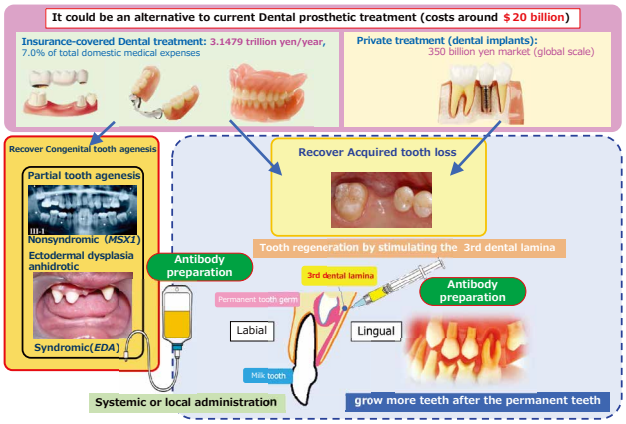
Registered VC

JIC Venture Growth Investments Co., Ltd.

Hands-on Representative
Venture Capitalist
URUNO Yoshiharu

Overview

We aim to develop a therapeutic drug that promotes the regeneration of autologous tooth tissue for congenitally tooth agenesis. Congenital tooth agenesis are diseases in which a person is born with one or more missing teeth, regardless of the type of tooth. It is classified into a mild type (hypodontia) in which five or fewer teeth are congenitally missing, and a severe type (oligodontia) in which six or more teeth are congenitally missing, with prevalences of 10% and 0.1%, respectively, and the severe type is reported to be hereditary. Genes responsible for congenital edentulism have been identified, including EDA1 and WNT10A, many of which are common in mice and humans. We found that supernumerary teeth were formed in mice lacking the USAG-1 protein (a BMP/Wnt antagonist), and identified a target molecule that can increase the number of teeth. Furthermore, we found that tooth formation was restored by crossing a congenital edentulism model mouse with a supernumerary tooth model mouse lacking the USAG-1 gene. Based on these research results, an anti-USAG-1 antibody will be produced to develop a treatment for congenital tooth agenesis and regenerate congenitally missing teeth. To date, a neutralizing antibody has been produced with the support of the AMED Project Promoting Support for Drug Discovery and other programs, intellectual property has been acquired, and Toregem BioPharma Co., Ltd. was established in May 2020. The final development candidate TRG035, a humanized anti-USAG-1 antibody, was shown to restore missing teeth in a single intraperitoneal/intravenous administration in a mouse beagle dog model of congenital edentulism. For the development of TRG035, we have currently completed the non-clinical trials and face-to-face consultation with the PMDA required for Phase 1 clinical trials, and finalized the outline of the protocol for Phase 1 clinical trials. Preparations for the Phase 1 clinical trials are being carried out in collaboration with industry, government and academia, including Toregem, Kyoto University, Kitano Hospital and AMED. Patients with congenital edentulism are edentulous from childhood, when the jawbone is still developing, making it difficult to adapt dentures or dental implants. It also leads to oral frailty (weakness of teeth and oral cavity) during growth period, which has a negative impact on nutritional intake and growth, and atrophy of the jawbone that supports the teeth. There has been a strong desire to the development of tooth regeneration therapy as a radical treatment. Although many studies have been attempted to regenerate teeth using tissue engineering techniques, they have not yet reached clinical application due to problems with cell resources, cost and safety. TRG035 has the potential to fundamentally change dental treatment. Toregem aims to create a society where people can eat with their own teeth throughout their lives by firstly regenerating teeth for congenitally tooth agenesis.



Company Info

Toregem BioPharma Co., Ltd.

President
KISO Honoka,
D.D.S., Ph.D.

Toregem Bio Pharma Co., Ltd. is a start-up venture from Kyoto University, established in May 2020 with the aim of researching, developing and launching a tooth regeneration treatment based on the research findings of Associate Professor Katsu Takahashi, Oral and Maxillofacial Surgery, Kyoto University (at the time of research, currently Chief of Dentistry and Oral Surgery, Medical Research Institute KITANO HOSPITAL, PIIF Tazuke-kofukai).
Our aim is to regenerate teeth by growing tooth buds (tooth germ), which would normally degenerate, with Anti- USAG-1 antibodies, which negatively regulates tooth development. We aim to extend healthy life expectancy by restoring missing teeth in patients with congenital tooth aganesis, regenerating the third dental lamina (the primary tooth organ that normally degenerates and disappears) after permanent teeth, and by improving oral function in the elderly.

Contact info“AT”toregem.co.jp
＊Replace “AT” with “@”.
Website https://toregem.co.jp/en/home_en

Subsidized Project

Development of MGT-006, a Treatment Drug for Ulcerative Colitis

Business Operator

Metagen Therapeutics, Inc.

Principal Investigator
Chief Scientific Officer
TERAUCHI Jun, Ph.D.

Registered VC

JIC Venture Growth Investments Co., Ltd.

Hands-on Representative
Venture Capitalist
HAYASHI Jun

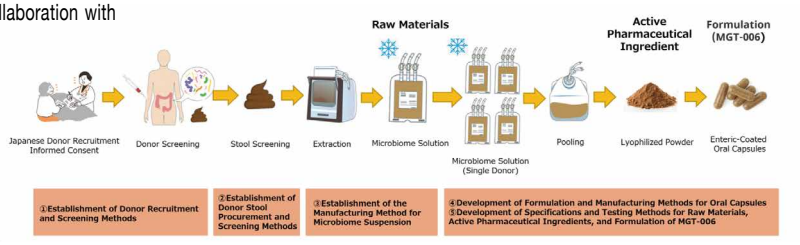
Overview

FMT (Fecal Microbiota Transplantation) is a treatment method in which intestinal microbiota derived from the stool of a healthy donor are transplanted into a patient, and is approved in the United States and Australia for the treatment of refractory Clostridioides difficile infections. This project aims to develop MGT-006, an oral FMT formulation for ulcerative colitis (UC), to obtain clinical POC.

Since 2014, Dr. Dai Ishikawa of Juntendo University conducted clinical research on FMT for patients with UC, of which intestinal microbiota solutions prepared in Juntendo hospital using healthy donor stools administered rectally via colonoscopy. In 2020, Metagen Therapeutics, Inc. was established for making this new FMT-based treatment a standard of care. In 2023, the Ministry of Health, Labor and Welfare of Japan approved Juntendo University to start a clinical study of this treatment as Advanced Medical Care B Program, which allows four designated research hospitals to provide FMT treatments for UC patients and the results will be used for an application package to obtain approval as a standard medical procedure. On the other hand, in order to provide this treatment as a new option to patients around the world, it is required to manufacture FMT at a commercial quality level, obtain clinical evidence through clinical trials, and obtain approval globally. Metagen Therapeutics has been developing MGT-006, an FMT-based drug for UC, in collaboration with Juntendo University.

Metagen Therapeutics retrospectively analyzed intestinal microbiota samples from donors and patients participated in previous clinical studies in Juntendo University, and established specifications for MGT-006. In addition, we found the optimal formulation to ensure viable bacterial counts during the lyophilization process of the stool suspension as an oral drug and confirmed its longitudinal stability, which led us to determine the final candidate formulation for MGT-006. Furthermore, the manufacturing site has been secured and the plan of the facility design has been completed. On the regulatory side, we have already started consultations with the PMDA. In the clinical trials of this project, we plan to conduct Phase I clinical trials in Japan, Europe, and the United States, and Phase II clinical trials will be conducted as an international joint clinical trial.

MGT-006 is a drug candidate that potentially offers a new treatment option for mild to moderate patients with UC by inducing and maintaining long-term remission and preventing the condition from becoming refractory or severe. Through this project, Metagen Therapeutics will develop the supply chain, including healthy stool procurement and the manufacturing of clinical trial drugs, and conduct non-clinical and clinical trials in compliance with regulatory requirements, and obtain a POC to complete the value chain. This will enable Metagen Therapeutics to possess a highly internationally competitive UC treatment pipeline with MGT-006. After obtaining the POC, the company will out-licence the drug to a pharmaceutical company for subsequent clinical trials and global launch, with the aim of providing a new FMT-based treatment to the patients globally.



Company Info

Metagen Therapeutics, Inc.

President and CEO
NAKAHARA Taku, Ph.D.

Metagen Therapeutics, Inc. is a biotech startup founded in 2020 with the mission of "Living up to the hopes of patients through microbiome science" and to create social impact through medical services and drug discovery based on gut microbiome research.
Co-founded by a gastroenterologist from Juntendo University and researchers from Keio University and Tokyo Institute of Technology, the company is promoting social implementation of Fecal Microbiota Transplantation (FMT) and FMT-driven reverse translational drug discovery. Currently, the company is focusing on development in the areas of immunological diseases (inflammatory bowel disease), oncology, and central nervous system diseases.

Contact contact"AT"metagentx.com
*Replace "AT" with "@".

Website https://www.metagentx.com/en/

Subsidized Project

Development of a novel cell therapy using vascular endothelial stem cells for intractable skin ulcers associated with systemic sclerosis

Business Operator

Revascular Bio Co., Ltd.

Principal Investigator
CEO
OMORI Kazuo, MD, PhD

Registered VC

OSAKA University Venture Capital Co., Ltd.

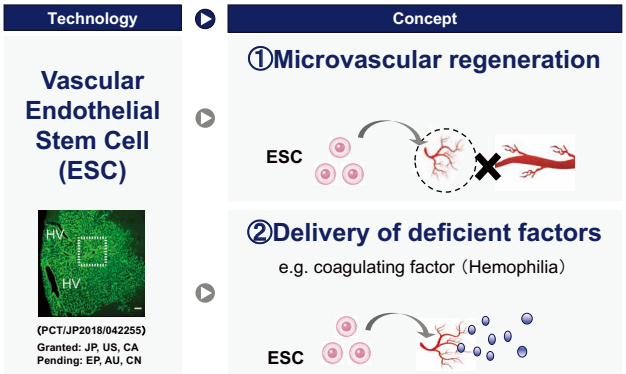
Hands-on Representative
Associate
TAGA Yuki

Overview

Systemic sclerosis, a rare disease that affects approximately 2.5 million patients worldwide and 30,000 in Japan, causes intractable skin ulcers due to impaired blood flow associated with vascular disorders. Current treatments such as vasodilators and antiplatelet drugs are not sufficiently effective.
The “vascular endothelial stem cells” discovered by the applicants that play a role in angiogenesis in the body not only support organ regenerative medicine by building blood vessels, but are also expected to be innovative solutions for many areas such as blood flow and drug supply to cancer. Furthermore, we succeeded in producing an organoid-like cell sheet that already has a vascular-like structure. For the healing of skin ulcers, applying this cell sheet to the ulcer will promote wound healing by increasing blood flow through angiogenesis.
We established a culture method for human vascular endothelial cell sheets and demonstrated in an animal model that transplantation of the sheets promotes ulcer healing through increased blood flow. In order to implement this technology clinically, this project aims to establish a commercial-scale manufacturing method and non-clinical trials in stage 1, complete first in human trials in Japan in stage 2, and complete Ph1/2 trials in the United States in stage 3.

Skin ulcers associated with systemic scleroderma often occur on the distal extremities, are easily intractable, and cause severe pain in the fingertips that persists for years, functional impairment, and the risk of limb amputation. We will develop vascular endothelial stem cell technology to resolve such pain early. Furthermore, we aim to expand the indication of our technology, which is highly unique worldwide, to cell therapy for diseases such as heart disease, dementia, and hemophilia.

Unprecedented vascular cell therapy



Company Info

Revascular Bio Co., Ltd.

CEO
OMORI Kazuo,
MD, PhD

Revascular Bio is a startup with the mission to deliver endothelial stem cells as pharmaceuticals to enhance the lives of patients. Blood vessels” are the largest organs, extending throughout the body. Their wide-ranging functions, including delivering oxygen and nutrients, and secreting proteins are essential for life activities and maintaining health.
Our core technology, “vascular endothelial stem cells”, are play the leading role in such dynamic changes in blood vessels in living organisms. A Co-founder Professor Takakura of Osaka University was the first in the world to discover these cells, and has since proven revolutionary efficacy against various vascular diseases.
Effective treatments have been notably lacking especially for microvascular disorders, and as a result, numerous patients continue to endure their suffering.
In order to revolutionize this current situation, we are fully committed to developing vascular endothelial stem cell technology as a new cell medicine and delivering it to patients' lives.

Contact https://revascularbio.com/en/

Website https://revascularbio.com/en/contact/

Consulting service

Now accepting interview (individual consultations) regarding applications.

*Individual consultations will not be provided during the application period.

- Persons eligible for consultation:VCs and Pharmaceutical Startups who are considering applying for this program.
- Consultation process:Please send an e-mail to the address above with your consultation matters.
- Implementation method:Online (web conference) or face-to-face interview

Contact

E-mail: v-eco“AT”amed.go.jp

Division of Technology Transfer, Department of Intellectual Property and Technology Transfer,
Japan Agency for Medical Research and Development (AMED)

*Replace “AT” with “@”.

Japan Agency for Medical Research and Development

Strengthening Program for Pharmaceutical Startup Ecosystem

Division of Technology Transfer,
Department of Intellectual Property and Technology Transfer

https://www.amed.go.jp/program/list/19/02/005_00014.html

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