Strengthening Program for Pharmaceutical Startup Ecosystem



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



Chief Regulatory and Development Officer

Newton Biocapital Partners

WADA Michihiko

Program Objective

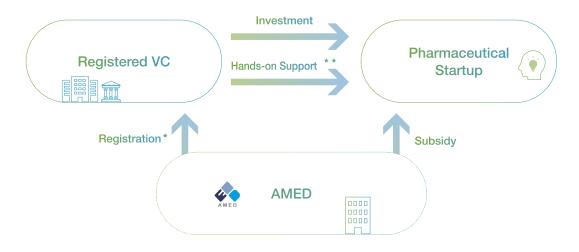
In order to strengthen the Pharmaceutical Startup Ecosystem in Japan, we aim to build the effective and synergistic cycle by creating as many successful examples of global standards as possible.



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

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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.

List of Registered VCs

(As of August 2025)

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4BIO Partners LLP



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4BIO Capital ('4BIO') is an international venture capital firm headquartered in London, focused solely on the advanced and emerging therapies sector. The 4BIO team, which has an unrivalled network within the advanced therapy sector, comprises leading advanced therapy scientists and experienced life science investors.

The firm maintains a global footprint across the UK, US, Europe and Asia with an objective to create, invest in, support, and grow early-stage companies. Its ultimate goal is ensuring access to potentially curative therapies for all patients, with a specific focus on viable, high-quality opportunities in precision medicine.

The 4BIO team consists of leading scientists in advanced therapies and experienced life sciences investors. 4BIO possess both an extensive network within the advanced therapy sector and the ability to select the best investment opportunities to support global business growth. Leveraging our strong relationships with stakeholders in Japan, we aim to connect the science and technology originating in Japan with global business opportunities. (https://www.4biocapital.com/)



erson in charge





Philippe Fauchet

Kieran Mudryy



Dima Kuzmin

ANRI Inc.



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ANRI Inc. is a Tokyo-based venture capital firm with extensive experience in seed and early-stage investments, providing support from the inception of business establishment. ANRI is dedicated to fostering technology-driven startups with the potential for global impact, including early-stage investments in biotech ventures focused on innovative drug development. Our team provides comprehensive support in areas such as team building, business strategy, and intellectual property, leveraging both ANRI's internal expertise and a vast network of specialized professionals. Through this AMED grant project, we aim to accelerate R&D and clinical development, transforming cutting-edge technologies from Japan's academic and research communities into groundbreaking therapeutic solutions.







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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 prestartup 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.







Ken Horne





HASHIMOTO Jun





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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.







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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



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Blackstone is the world's largest alternative asset manager. We seek to deliver compelling returns for institutional and individual investors by strengthening the companies and assets in which we invest. Blackstone Life Sciences focuses on funding clinical development of innovative medicines and medical technologies. Our goal is to bring vital medicines and technologies to market by designing, funding and executing clinical trials for products. Blackstone Life Sciences combines its clinical, commercial and operational expertise with Blackstone's global network, access to capital, and infrastructure. We commit our skill and scale to select, fund and advance what we believe to be the most promising life science products and companies through hands-on involvement and directly applied expertise.







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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 Seattle, Washington. Learn more at website.



Person in charge



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D3LLC



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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.



Person in charge





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Kenji



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DBJ DBJ Capital Co., Ltd

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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.



MITSUGUCHI Hisashi



YASUDA Yorinobu

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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





YOKOTA Junichi

Shoma



NIIMI Yuka

Eight Roads Ventures Japan

(Eight Roads Capital Advisors Hong Kong Limited)



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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



KOMOTO Shinichiro



ASHIDA Hiroki

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Eisai Innovation, Inc. serves as the corporate venture capital arm of Eisai Co., Ltd. and engages in global investment activities in the areas of neurology, oncology, and global health. Our team of professionals has extensive experience in drug discovery, as well as investment and business development. We work closely with and support entrepreneurs both financially and collaboratively in their pursuit for impactful therapeutics.



eisai innovation



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EQT Life Sciences



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EQT Life Sciences, part of EQT Group, a global investment firm, is looking to invest in private, early-stage life sciences companies. With over 30 years of experience, EQT Life Sciences has raised more than €3.5 billion and invested in over 150 private companies. The investment team based in Amsterdam, Boston & Munich actively sources investments in highly innovative technologies that could be transformational for patients' lives.







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Vincent Brichard



Laurenz Govaerts

F-Prime Capital Partners

(Impresa Management LLC)



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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





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Hiroki





Robert Weisskoff

Brian Yordy

Fast Track Initiative, Inc.



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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.



Person in charge



KIRIYA Keita

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We deeply understand and 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, to help realize their business vision. Our life science team consists of venture capitalists with deep expertise in drug discovery, medical devices, and healthcare. We provide risk capital and a strong commitment to our portfolio companies, aiming to develop new treatments for patients with significant unmet medical needs. To deliver scientific technology from Japan to patients worldwide, we also proactively engage in company creation from the perspective of a "CO-FOUNDER."





JAFCO



KITAZAWA



ISHIMOTO



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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.



Person in charge





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Keio Innovation Initiative, Inc. (KII) is dedicated to its mission: "Let us help your research, your invention, your innovation change the world." We invest in the deep tech start-ups originating from Japanese leading universities and research institutions other than Keio University and, providing hands-on support to drive forward the incorporation of excellent results into society. For this program specifically, we invest in start-ups at various stages, from drug discovery to clinical trials, and support the advancement of both clinical and business development.



Person in charge



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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.







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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.







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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 industryacademia 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.







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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



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Newton Biocapital Partners





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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.



SUZUKI



NEWTON

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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.





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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 companies 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



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Saisei Ventures is a life science venture capital firm dedicated to building nextgeneration companies in the healthcare sector. We create ventures that start from bold ideas and empower dynamic entrepreneurs by providing technical, operational, and financial guidance. Our approach combines Western expertise and Japanese innovations to build globally competitive companies that will have the greatest impact on patient lives. With operations in Japan and the United States, Saisei aims to enhance the value of its portfolio by leveraging its unique networks and the institutional advantages of both countries. For more information, please visit https://www. saiseiventures.com/.







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Taiho Innovations is the corporate venture capital arm of Taiho Pharmaceutical, a Japanese specialty pharmaceutical company focused on oncology and immunologyrelated diseases. We invest in early-stage Japanese biotech startups with promising seeds and platform technologies for drug discovery. In addition, Taiho Innovations is actively engaged in incubation programs for academia, supporting researchers in testing and growing their game-changing ideas as well as launching new startup companies. Our team has extensive experience in both international investment and pharmaceutical R&D, enabling us to provide not only financial backing but also comprehensive, handson support to improve human health globally.







SHIMOMURA Toshiyasu

MORI

Fumitaka





MIYAKOSHI Hitoshi

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Taiho Ventures, LLC



TAIHO VENTURES

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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.



ASANUMA Sakae



ISHII Takaaki

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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.





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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.





OHORI Makoto (Mark), Ph.D.



BINGO Atsuhiro (Atsu), Ph.D.

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)	Up to September 2031
#2	Innovative technological development for development of pharmaceuticals etc. for diseases other than infectious diseases.	AMED Subsidy covers up to 2/3 of the expenses.	(Set for each Adopted Project)

- 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.

List of Adopted Projects

(As of August 2025)

Development of an innovative thrangeutic agent for myotonic dystrophy type I by a sequence-specific RNA binding protein targeting pathogenic CUG-repeat RNA 1792023 Development of ENDOPIN, a one-of-a-kind oral analysesic that activates the decording pain suppression pathway Glinical proof of concept study of CZY-SS6, a human IPS cell-derived cardiomycoyte. Glinical proof of concept study of CZY-SS6, a human IPS cell-derived cardiomycoyte. Glinical proof of concept study of CZY-SS6, a human IPS cell-derived cardiomycoyte. Glinical proof of concept study of CZY-SS6, a human IPS cell-derived cardiomycoyte. Glinical proof of concept study of CZY-SS6, a human IPS cell-derived cardiomycoyte. Processor Study of the study of	Adoption		(As of August	2025)
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FY2025 Development of ferroptosis inducing anti-cancer therapy utilizing novel mechanism FerroptoCure Inc. 32	FY2025		C4U Corporation	32
	FY2025	Development of ferroptosis inducing anti-cancer therapy utilizing novel mechanism	FerroptoCure Inc.	32

R&D Project

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

Registered VC

Newton Biocapital Partners

R&D Principal Investigator

CSO Board of Directors NAKANISHI Osamu, Ph.D.

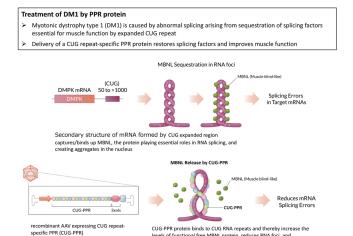
Business Operator

EditForce, Inc.
President and CEO
ONO Takashi, Ph.D.



Overview

We have developed a proprietary technology using plant-derived PentatricoPeptide Repeat (PPR) motifs to design artificial proteins that can bind specifically to target RNA sequences. Leveraging this technology, we are developing a first-in-class therapeutic aimed at suppressing the pathogenicity of CUG repeat RNA, the genetic cause of myotonic dystrophy type 1 (DM1), a currently untreatable rare genetic disorder. In disease model mice, a single administration of an AAV vector expressing the PPR protein resulted in significant symptom improvement and long-lasting efficacy. We are currently conducting safety evaluations and establishing the manufacturing process with the goal of submitting an IND application in 2026. This technology is expected to serve as an innovative RNA-targeted therapy with potential applications to other diseases.



Contact

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

Website

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



Adopted Project in FY2023

R&D Project

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

Business Operator

BTB Therapeutics GK Chief Executive Officer KIYOIZUMI Takashi MD, PhD



Registered VC

Kyoto University Innovation Capital Co., Ltd.

(R&D Principal Investigator

Head of R&D OGIKU Tsuyoshi Ph.D.

Overview

ENDOPIN is an oral analgesic compound with a novel mechanism of action, discovered from Kyoto University's original compound library. ENDOPIN, a selective inhibitor of the adrenergic receptor α 2B, increases noradrenaline release in the dorsal horn of spinal cord through negative feedback caused by α 2B inhibition, activating the descending pain inhibition pathway, thereby producing analgesic effects. ENDOPIN showed strong analgesic effects comparable to those of opioids including morphine, but without opioid related side effects, such as sedation, respiratory depression or GI symptoms, even at more than 100 times the effective dose, 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.

Pain

Ascending

Pain

Ascending

Pain

Ascending

Pain pathway

Pain pathway

Pain pathway

Contact

contact"AT"btbtherapeutics.com
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Website

https://www.btbtherapeutics.com/en/



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



Registered VC

Kyoto University Innovation Capital Co., Ltd.

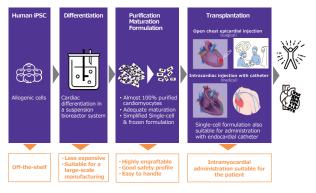
R&D Principal Investigator

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

Overview

Many cases of severe chronic heart failure are resistant to drug therapy, and for these patients, heart transplantation is considered to be the only treatment option. We have developed a new technology to efficiently produce highly engraftable and highly pure cardiomyocytes, named "OZTx-556," from human iPS cells. In transplantation experiments using animal models of myocardial infarction, these cells demonstrated excellent engraftment and a significant improvement in cardiac function. However, it is expected that hundreds of millions of cells will be required for actual treatment, making it essential to establish technology that can produce high-quality cells in large quantities at low cost. In this project, we aim to develop an inexpensive and efficient largescale manufacturing process using suspension culture, with a view toward commercial-scale production. In addition, we are developing a novel catheter-based delivery method to minimize the physical burden on patients, and will compare this with the conventional open-chest administration to select the optimal

delivery method. Our ultimate goal is to use these technologies to obtain proof of concept (PoC) for therapeutic efficacy in global clinical trials and deliver this treatment to as many patients as possible.



Contact

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

Website

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



Adopted Project in FY2023

R&D Project

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

Business Operator

Restore Vision Inc.
CEO / CMO
KATADA Yusaku, MD, Ph.D.



Registered VC

Remiges Ventures, Inc.

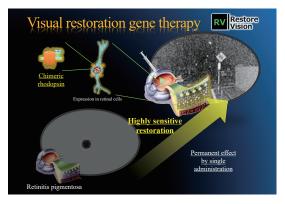
(R&D Principal Investigator)

CEO / CMO KATADA Yusaku, MD, Ph.D.

Overview

Retinitis pigmentosa (RP), a representative inherited retinal disease with significant unmet medical needs globally, is the second leading cause of blindness in Japan and, like other inherited retinal diseases, still lacks effective treatments whose urgent development is direly needed. To address this challenge, we are developing RV-001—a visual restoration gene therapy utilizing our proprietary light-sensor protein, Chimeric Rhodopsin. Although RP has diverse genetic causes, our therapy restores vision by providing light sensitivity to remaining retinal cells, making it applicable regardless of gene mutation. RV-001 employs a highly sensitive enzymatic-type optogenetic approach, offering the potential for practical vision restoration that existing technologies have struggled to achieve. Furthermore, by using an adeno-associated virus (AAV) vector, long-lasting therapeutic effects can be expected from a single administration. Leveraging our advantages in patient access, clinical infrastructure, and

Japan's favorable regulatory environment, our goal is to obtain proof-of-concept (POC) through domestic and subsequent international clinical trials.



Contact

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

Website

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



R&D Project

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

R&D Principal Investigator



Chief Executive Officer ARIMOTO Itaru, PhD.

Business Operator

Neusignal Therapeutics, Inc. Chief Executive Officer ARIMOTO Itaru, Ph.D.



Overview

To address one of the global challenges, Alzheimer's disease (AD), we aim to develop orally available small molecule therapeutics with novel mechanisms of action.

The founder, Dr. Shigeki Moriguchi, associate professor at Tohoku University, and his colleagues discovered that the KATP channels, 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.

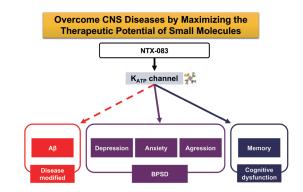
Furthermore, some results suggest disease-modifying effects of this compound, and we expect that NTX-083 would be a breakthrough treatment for AD that improves both core and peripheral symptoms.

In this project, we develop NTX-083 globally by leveraging the strengths of NTX-083, and will clarify its unique mechanism Fast Track Initiative, Inc.

in healthy subjects) is ongoing.

Registered VC

of action through more detailed research. As of August 2025, Phase1(Randomized, double-blind, placebo-controlled, safety, tolerability and pharmacokinetic study of escalating single dose



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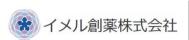
Adopted Project in FY2023

R&D Project

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

Business Operator

Imel Therapeutics, Inc. Representative Director **INABA** Taro



Registered VC

Remiges Ventures, Inc. RDiscovery, KK

R&D Principal Investigator

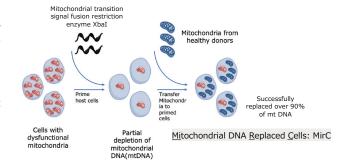
Chief Project Officer KAMIYA Yuki

Overview

Cancer immunotherapy has made significant progress with the advent of immune checkpoint inhibitors and CAR-T therapy, but there are still many patients who do not respond to treatment. One of the factors contributing to this is the exhaustion and aging of immune cells, including T cells,

Recent studies have shown that abnormalities in mitochondrial function are associated with these conditions. In exhausted or aged T cells, mitochondrial function is impaired, and the ability to remove damaged mitochondria is also disrupted. Therefore, restoring mitochondrial function is considered an effective way to improve T cell function.

However, there are currently no treatment methods that directly restore these functions and enhance cancer immunity. To address this challenge, Imel Therapeutics has identified the potential to improve exhaustion and aging by replacing mitochondria in T cells and is aiming for clinical application. This technology will enhance the efficacy of immunotherapy for patients who have not previously achieved sufficient results. thereby significantly contributing to expanding treatment options for cancer and extending healthy life expectancy.



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https://imel-therapeutics.com/



R&D Project

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

(R&D Principal Investigator)



Representative Director HITOSHI Yasumichi, MD,PhD

Business Operator

Shinobi Therapeutics Co. Ltd. Representative Director HITOSHI Yasumichi, MD, PhD SHINOBI

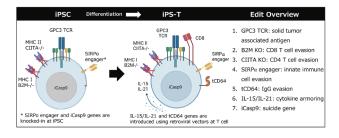
Impresa Management LLC

Registered VC

Overview

CAR-T cell therapy has garnered significant attention as a nextgeneration cancer immunotherapy. However, its manufacturing requires patient-derived T cells, making it challenging to secure a stable supply of consistent quality and quantity, and leading to high costs. To overcome these challenges, Shinobi Therapeutics Co., Ltd. is developing "NJA-001," an allogeneic iPS cell-derived T-cell therapy product designed for repeated administration while avoiding rejection. NJA-001 has several key features, 1) Targets GPC3, which is highly expressed in hepatocellular carcinoma and other cancers, demonstrating potent and tumorspecific cytotoxicity.2) Avoids rejection, allowing for repeated administration. 3) Is an off-the-shelf product that does not require patient blood. These characteristics make NJA-001 a promising and effective treatment option for patients who have not responded to existing therapies. NJA-001 is manufactured at Center for iPS Cell Research and Application (CiRA) at Kyoto University. Phase I clinical trials are planned at the Kyoto

Innovatioin Center for next generation clinical trials and iPS Cell Therapy at Kyoto University Hospital, the National Cancer Center Hospital East, and the Cancer Institute Hospital of Japanese Foundation for Cancer Research. Additionally, Phase Ib clinical trials are being planned to include US sites. Through this project, we aim to establish human proof-of-concept for NJA-001 and contribute to strengthening Japan's healthcare ecosystem.



Contact

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Website

https://www.shinobitx.com/



Adopted Project in FY2023

R&D Project

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

Business Operator

Periotherapia Co.,Ltd. President CEO&COO TAHARA Eiji,Ph.D..



Registered VC

OSAKA University Venture Capital Co., Ltd.



President CEO&COO TAHARA Eiji, Ph.D.

Overview

We are anThe University of Osaka-based drug discovery venture developing antibody therapeutics for intractable diseases. Our strength lies in a comprehensive portfolio combining therapeutic antibodies and diagnostic development.

Our lead pipeline targets intractable metastatic/recurrent HER2-negative breast cancer. We launched domestic clinical trials in March 2025 with U.S. trials progressing smoothly. Treatment-resistant triple-negative breast cancer remains a significant global challenge.

We discovered "Pathological periostin," a key factor inducing anticancer drug resistance, and identified its disease-specific variants. This enabled us to develop variant-specific antibodies with enhanced safety and tumor specificity.

The global HER2-negative breast cancer market is worth 440 billion JPY. Our platform shows potential for other diseases and antibody-drug conjugate co-development. We are advancing clinical trials in Japan and the U.S. while

pursuing early out-licensing.

This innovative treatment will bring hope to AYA generation women worldwide. Our vision is to become a leading global specialty pharma representing Japan.

Periotherapia drug discovery strategy

"Periotherapia leverages our proprietary drug discovery assets to create therapeutics for a wide variety of diseases."



Contact

https://periotherapia.co.jp/en/contact/

Website

https://periotherapia.co.jp/en/



R&D Project

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

Business Operator

United Immunity, Co., Ltd. President KISHIDA Masato, Ph.D, MBA.



Registered VC

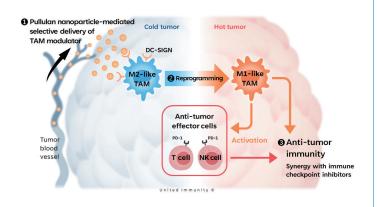
The University of Tokyo Edge Capital Partners Co., Ltd.



Chairman, Head of R&D HARADA Naozumi

Overview

We generated UI-102, a new pullulan nanogel 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 toxicology study in animals showed good safety profile. 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.



Contact

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

Website

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



Adopted Project in FY2024

R&D Project

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

Business Operator

AdipoSeeds, Inc. CEO&CFO FUWA Junji



Registered VC

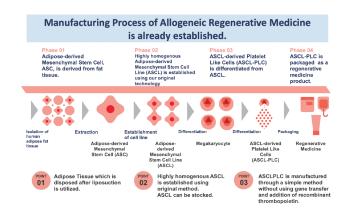
DCI Partners Co., Ltd.

R&D Principal Investigator

CSO MATSUBARA Yumiko, PhD

Overview

AdipoSeeds established a technique for manufacturing process of ASCL-PLC as allogenic regenerative medicine using human adipose tissue without using gene-transfer, etc. Technology is based on the finding that the differentiation determinants of platelets are inherent in mesenchymal stem cell, and the expression of these factors is slight during the maintenance culture, however, these expressions increase in a culture day-dependent manner when cultured with platelet differentiation-inducing medium containing transferrin. In this project, AdipoSeeds will develop ASCL-PLC for the treatment of intractable skin ulcers. New treatment is desired because intractable skin ulcers require a long period of treatment and have a high recurrence rate. AdipoSeeds aims to complete an exploratory clinical trial and establish POC by 2027.



Contact

03-6822-0325 info"AT"adiposeeds.co.jp *Replace "AT" with "@".

Website

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



R&D Project

Development of SFG-02 for underactive bladder

R&D Principal Investigator

Board member, Chief Scientific Officer TANAKA Akira,

Business Operator

Juro Sciences Inc.
Representative Director, CEO
NAGABUKURO Hiroshi,PhD



Miyako Capital Inc.

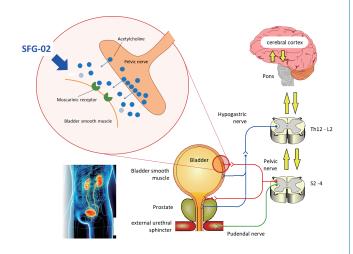
Registered VC

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 to void, 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.

After confirming the pharmacokinetics and safety and tolerability of SFG-02 in the Phase I study, we plan to conduct Phase 2a 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.



Contact

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

Website

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



Adopted Project in FY2024

R&D Project

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

Business Operator

PRD Therapeutics, Inc.
Representative Director
HOSODA Kanji, Ph.D



Registered VC

JAFCO Group Co., Ltd.



Representative Director HOSODA Kanji, 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

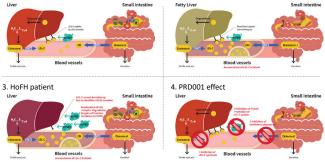
1. Healthy person (MASLD)

HoFH is a rare-hereditary disease caused by a mutation in the LDL receptor-related genes. 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.

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.

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

2. MASH/MASLD patient



Contact

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Website

https://prdtherapeutics.com/en/



R&D Project

Development of a new LAT1 inhibitor for multiple sclerosis

R&D Principal Investigator



Clinical Development and Regulatory Affairs Department KATAYAMA Sota

Business Operator

J-Pharma Co., Ltd. Representative Director and President & CEO YOSHITAKE Masuhiro

J-Pharma

Overview

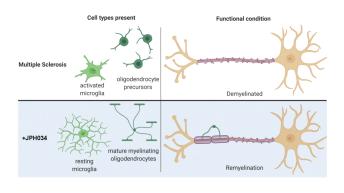
Multiple sclerosis (MS) is the most common chronic inflammatory demyelinating neurological disease in young adults. The number of patients with multiple sclerosis is estimated to be 18,000 patients in Japan. It develops as relapsing-remitting disease and progresses to secondary progressive MS, which is marked by the development of permanent neurological deficits and progressive clinical disability. Many medications for the treatment of MS have been approved as disease-modifying therapies. However, their efficacy relatively diminishes as the disease progresses with chronic central local inflammation, defined as smoldering MS, becomes predominant. 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, a LAT1 non-competitive inhibitor discovered by Osaka University, inhibits microglial activation and promotes the remyelination.

Hong Kong Limited

Eight Roads Capital Advisors

Registered VC

We will determine the efficacy of JPH034 as a treatment for progressive MS, a disease with a high unmet need.



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



Adopted Project in FY2024

R&D Project

Research and Development of an autologus therapy using Novel CAR-T having GITRL for refractory GD2positive solid tumors

Business Operator

T Cell Nouveau Inc. MATSUNAGA Kosuke



Registered VC

DBJ Capital Co., Ltd.



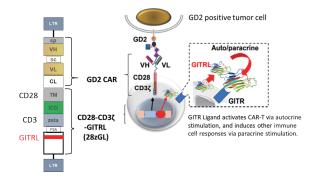
Chairman TAKESAKO Kazuto, Ph D

Overview

CAR-T therapy for solid tumors are not successful due to the various reasons. This project aims to develop a novel CAR-T therapy for refractory solid tumors. This CAR-T is targeting GD2 ganglioside, one of the glycolipids, expressed on the surface of various tumor types. The CAR features are as follows:1) The scFv of a highly specific murine monoclonal anti-GD2 antibody is applied as the external domain;2) The CAR has a novel gene structure, installing GITRL (glucocorticoid-induced TNF receptor related protein ligand) as secreting co-stimulating molecule. Furthermore, in order to manufacture the GD2 GITRL CAR-T, a completely closed automatic cell manufacturing system will be used, which we can expect cost reduction due to following reasons:1) Each step check is not necessary;2) Large amount investment for manufacturing facility is not necessary. Also, for pediatric patients, the blood draw amount will be limited, and we will establish CAR-T manufacturing process using apheresis

product as a starting material, then we will conduct a clinical trial for refractory neuroblastoma.

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



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

https://www.tcellnouveau.com/en



R&D Project

Development of a new antibody drug to treat congenital tooth agenesis

R&D Principal Investigator



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

Business Operator

Toregem BioPharma Co., Ltd.
President
KISO Honoka, D.D.S., Ph.D.

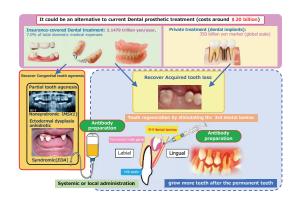


JIC Venture Growth Investments Co., Ltd.

Registered VC

Overview

Congenital edentulism is a condition in which a person is born without teeth, and EDA1 and WNT10A have been identified as causative genes, many of which are common in mice and humans. The only alternative treatment is dentures or dental implants in adulthood, and tooth regeneration therapy has been strongly desired as a curative treatment. We found that excess teeth form in USAG-1 gene-deficient mice and identified the target molecule, showing that the number of teeth can be increased by one type of protein. We also found that tooth formation was restored by crossing USAG-1 gene-deficient mice with a mouse model of congenital edentulism and a mouse model of excessive teeth. Humanised anti-USAG-1 antibody TRG035 was found to restore absent teeth after a single administration in congenital edentulism model mice beagle dogs. PMDA face-to-face advice completed and protocol finalised. In collaboration with industry, government and academia, Ki-CONNECT, Kyoto University Hospital, Kitano Hospital of the Institute of Medical Research, Toregem Biopharma and AMED, a phase I clinical trial in healthy subjects has been underway since October last year, lasting approximately one year.



Contact

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Website

https://toregem.co.jp/en/



Adopted Project in FY2024

R&D Project

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

Business Operator

Metagen Therapeutics, Inc. President and CEO NAKAHARA Taku, Ph.D.



Registered VC

JIC Venture Growth Investments Co., Ltd.



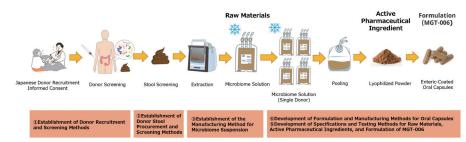
Chief Scientific Officer TERAUCHI Jun, Ph.D.

Overview

Fecal microbiota transplantation (FMT) is a therapeutic approach involving the transfer of gut microbiota derived from healthy donor stools into patients. It is approved in the United States and Australia as a treatment for refractory Clostridioides difficile infections. Since 2014, Juntendo University has conducted clinical research on FMT for ulcerative colitis (UC), and based on

this research, Metagen Therapeutics was established in 2020. To offer this treatment as a new therapeutic option for patients worldwide, we are developing an oral FMT formulation called "MGT-006." We have established optimal formulation and manufacturing processes, and

initiated discussions with regulatory authorities, including the PMDA and FDA. Moving forward, we aim to conduct clinical trials domestically and internationally to obtain POC. MGT-006 represents a novel therapeutic option for patients with moderate UC, aiming to induce and sustain long-term remission and prevent disease progression to refractory or severe conditions.



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Website

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R&D 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. CEO OMORI Kazuo, MD, PhD

REVASCULAR BIO

Registered VC

OSAKA University Venture Capital Co., Ltd.



CEO OMORI Kazuo, MD, PhD

Overview

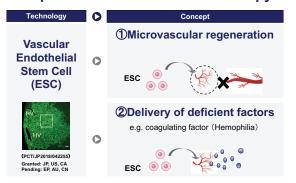
Systemic sclerosis (SSc), a designated intractable disease affecting approximately 2.5 million people worldwide and about 30,000 in Japan, causes refractory skin ulcers due to microvascular damage. Currently, there are few treatment options that effectively improve blood flow, and patients often suffer from chronic severe pain and functional impairment.

The applicants were the first in the world to identify vascular endothelial stem cells (VESCs), which play a key role in angiogenesis in vivo. Animal studies have demonstrated that applying these cells to ulcer sites promotes angiogenesis and enhances local blood flow, thereby accelerating wound healing.

This project aims to develop VESCs into a cell-based therapeutic product. We will establish a robust manufacturing process, conduct non-clinical studies, and proceed with First-in-Human (Ph1/2) clinical trials in Japan, followed by Ph1/2 trials in the United States. The successful realization of this project will bring relief to patients

suffering from refractory skin ulcers and may further contribute to the development of new treatments for other unresolved vascular diseases, such as heart disease and dementia.

Unprecedented vascular cell therapy



Contact

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

Website

https://revascularbio.com/en/



Adopted Project in FY2024

R&D Project

Development of a novel ex vivo expanded Hematopoietic Stem Cell therapy product for rare pediatric blood diseases

Business Operator

Celaid Therapeutics Inc.
President and CEO
ARAKAWA Nobuyuki



Registered VC

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

R&D Principal Investigator

Board Director,

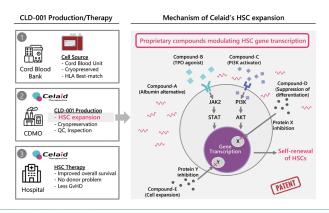
COO/CFO
INOUE Yusuke

Overview

This project aims to obtain clinical proof of concept (POC) in the U.S. for CLD-001, our novel hematopoietic stem cell (HSC) therapy product targeting severe and rare pediatric non-malignant hematologic diseases. The target indications include aplastic anemia and primary immunodeficiency for which allogeneic HSC transplantation is currently the only curative option. However, existing therapies face critical challenges:

- $\begin{tabular}{ll} \begin{tabular}{ll} \beg$
- (2) shortage of bone marrow donors, and
- (3) severe graft-versus-host disease (GvHD) after transplantation. Focusing on the epigenetic regulation of HSC gene expression, we have established a proprietary technology using chemical compounds to robustly expand CD34⁺ cells with high purity and long-term engraftment capability. CLD-001 is designed to overcome challenge (1), and by using cryopreserved umbilical cord blood (UCB) as the cell source, also addresses challenges (2) and

(3). We are currently advancing process development with a U.S.-based CDMO, and plan to proceed with GMP manufacturing, GLP-compliant safety studies, and a Phase 1/2 clinical trial in the U.S.



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R&D Project

Development of antigen-specific immune cell therapy against autoimmune liver diseases

R&D Principal Investigator



Representative Director Michael V. McCullar, Ph.D., MBA

Business Operator

RegCell Co., Ltd.
Representative Director
Michael V. McCullar, Ph.D., MBA



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

Registered VC

Overview

RegCell Co., Ltd. develops and manufactures autologous regulatory T-cell (Treg) therapeutics. Our lead candidate, RegPD101, harnesses patient-derived Tregs with high biocompatibility, potent functionality, and robust stability to pursue a curative approach for autoimmune diseases. Leveraging proprietary epigenetic reprogramming

technology developed by Dr. Shimon Sakaguchi and Dr. Norihisa Mikami, we have established a genemodification-free process to massproduce highly pure, antigen-specific Tregs, and have demonstrated in vivo proof-of-concept in multiple autoimmune and inflammatory disease models. Under this program, we will target autoimmune indications with high unmet medical needs and

market potential, utilize Tregs manufactured by a U.S. GMP-compliant CDMO, and aim to achieve clinical proof-of-concept in the U.S. and other regions based on in vitro and in vivo efficacy and safety data. Through collaboration with a robust U.S. biotech ecosystem, we will drive an optimal development and commercialization strategy.



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Adopted Project in FY2024

R&D Project

Development of pH-responsive polymeric micelles selectively delivering IL-12 to solid tumors for non-responders against existing immunotherapy

Business Operator

Red Arrow Therapeutics, KK Representative Director, CEO TAJIMA Rika, MPH



Registered VC

Beyond Next Ventures Inc.



Representative Director, CEO TAJIMA Rika, MPH

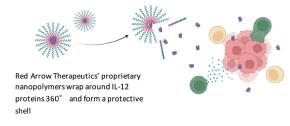
Overview

IL-12 is a protein naturally present in the body that supports immune function. For decades, researchers have explored the idea of using IL-12 to boost the immune system and treat cancer by delivering it directly to tumor tissues. However, IL-12 causes severe systemic toxicity, making it difficult to safely develop as a drug.

At Red Arrow Therapeutics, we are tackling this challenge using our patented pH-sensitive nanopolymer technology. By encapsulating IL-12 within these nanopolymers, we can prevent its harmful effects throughout the body after systemic administration. The nanopolymer shell remains intact during circulation but responds to pH changes near the tumor, opening up to release IL-12 precisely at the cancer site. This approach allows IL-12 to concentrate on the tumor while minimizing side effects.

The goal of Stage 1 is to gather animal study data to confirm whether the nanopolymer-encapsulated IL-12 is both effective and less toxic. Additionally, since the drug is currently produced only

in small quantities in the lab, we will begin exploring the feasibility of large-scale manufacturing to ensure it can be made in sufficient amounts for widespread patient use.



pH change triggers the shell to break and release IL-12 precisely at the tumor site. This recruits other immune cells such as T cells, B cells, dendric cells etc. and boosts the immune system, killing the cancer cells

Contact

03-6820-0861

Website

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R&D Project

Development of a novel gene therapy for the neurodegenerative disease

R&D Principal Investigator

Representative Director, CSO TSUJI Shinnosuke, PhD,

Business Operator

reverSASP Therapeutics Co., Ltd. Representative Director, CEO TORII Shinichi, PhD



Fast

Registered VC

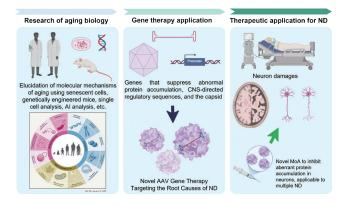
Fast Track Initiative, Inc.

Overview

Neurodegenerative diseases (ND) are caused by gradual damage to nerve cells in the brain, significantly affecting various brain functions, such as memory, motor function, and cognitive function in patients. It is well known that the risk of developing ND increases with age, and that aging is an important risk factor in accelerating disease onset and progression. In particular, the accumulation of abnormal proteins in the brain due to aging causes neuronal damage and dysfunction.

Currently, no treatment has been established to fundamentally halt the progression of ND. Therefore, there is a strong need to develop new treatments that act against the root cause of ND, and slow the progression of diseases or improve the symptoms.

The goal of this grant project is to develop novel gene therapy which can suppress abnormal protein aggregation in neurons by applying both scientific knowledge obtained from the latest aging research and proprietary technologies to create innovative drug for serious ND.



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Adopted Project in FY2024

R&D Project

Development of hypoimmune allogenic iPSC-derived CD19-CAR targeting Natural Killer cell therapy for autoimmune diseasescell-derived cytotoxic T cell therapy for GPC3-positive solid cancer

Business Operator

Shinobi Therapeutics Co. Ltd.
Representative Director
HITOSHI Yasumichi, MD, PhD



Registered VC

Impresa Management LLC

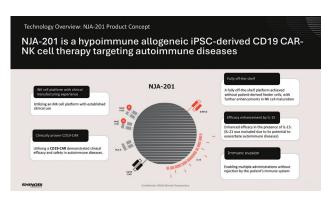
R&D Principal Investigator



Overview

Shinobi Therapeutics, Co., Ltd. aims to develop "NJA-201," a CD19-specific chimeric antigen receptor (CAR)-expressing, hypoimmune, allogeneic iPSC-derived natural killer (NK) cell therapy for autoimmune diseases. This therapeutic agent targets patients with autoimmune diseases such as systemic lupus erythematosus, lupus nephritis, and myasthenia gravis, who are refractory or resistant to existing therapies. Building on the manufacturing platform for iPSC-derived NK cells established during an investigator-initiated clinical trial of GPC3-specific CARexpressing allogeneic iPSC-derived NK cell therapy conducted by Kyoto University's Center for iPS Cell Research and Application (CiRA) and the National Cancer Center, the development of NJA-201 introduces new technologies such as IL-15 armoring and hypoimmune gene editing. These advancements aim to enhance therapeutic efficacy and avoid immune rejection. The project plans to conduct non-clinical studies through Phase Ib clinical

trials to establish human proof-of-concept. This effort is intended to resolve the drug lag in this disease area within Japan and contribute to strengthening the drug discovery ecosystem.



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Global Phase 2a Proof-of-Concept Clinical Trial of the Small Molecule Compound GXV-001 for Fragile X Syndrome

Registered VC

Mitsubishi UFJ Capital Co., Ltd.



Senior Director KOBAYASHI, Toshitake, PhD

Business Operator

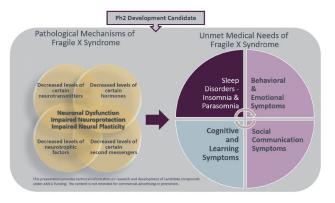
GEXVal Inc.
President and CEO
KATO, Juran, PhD



Overview

Fragile X Syndrome (FXS) is a rare neurodevelopmental disorder caused by mutations in the *FMR1* gene, characterized by diverse symptoms including intellectual disability, developmental delays, autism-like behaviors, ADHD-like behaviors, sleep disorders (insomnia, parasomnia, etc.), anxiety, and sensory hypersensitivity, each of which significantly impact the quality of life of patients and their families. Currently, no approved drug available. In Japan, approximately 5,000 patients are estimated to have FXS; however, the diagnostic rate remains significantly lower compared to other countries, with only a small number of patients currently diagnosed.

GXV-001 is a novel small molecule under development for neurological disorders. In preclinical studies, selectivity towards its target, activity against the molecular mechanisms underlying the pathology, and efficacy in FXS animal models have been evaluated. Phase I clinical trials in healthy volunteers achieved endpoints for pharmacokinetics and safety/tolerability, with proof-of-mechanism (POM) also confirmed. This project plans to conduct an Phase IIa clinical trial in FXS patients.



Contact

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Website

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Adopted Project in FY2024



Development of a gene therapy pipeline using mRNA-mediated Gene Writing for severe genetic diseases

Business Operator

Typewriter TX Japan GK
General Manager
YOSHIKAWA Mayu



Registered VC

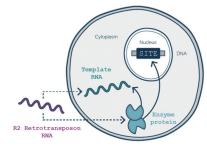
ANV Management, LLC

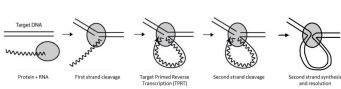


Head of R&D Japan ICHIKAWA Takashi, Ph.D.

Overview

Typewriter Therapeutics is a University of Tokyo spin-off biotechnology company developing next-generation gene editing technology, "Gene Writing," which enables the precise insertion of therapeutic genes into the genome. Building on cutting-edge transposon-based technologies, we aim to deliver innovative gene therapies for severe genetic disorders that currently lack effective treatments. With research hubs in Kashiwa, Chiba (Japan) and Cambridge, Massachusetts (USA), our mission is to bring groundbreaking innovations from Japan to patients around the world.





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https://www.typewritertx.com/



R&D Project

Development of Novel Anti-Cancer Drug by "Locking Inhibition" of Amino Acid Transporter R&D Principal Investigator



Chairman & CEO ASANO Tomoyuki

Business Operator

Atransen Pharma Ltd.

Chairman & CEO ASANO Tomoyuki
President & COO KAWAI Andrew Nobuhiro , Ph.D



JAFCO Group Co., Ltd.

Registered VC

Overview

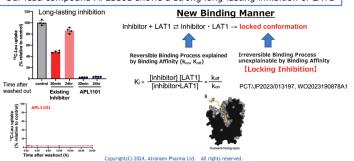
Atransen Pharma is a biotech venture specializing in the development of molecular targeted therapies that inhibit LAT1,

an amino acid transporter specifically overexpressed in cancer cells. The company leverages its proprietary screening platform and structure-based drug design as core strengths. Its lead compound, APL1101, is a rationally designed molecule based on the 3D structure of LAT1. It blocks the amino acid transport pathway of LAT1 and exerts a novel "locking inhibition" mechanism that suppresses tumor growth while offering a favorable safety profile. This project aims to complete non-clinical studies to determine human dosage and evaluate safety, followed by a Phase I and basket-type Phase IIa clinical trial, and a comparative Phase IIb trial to establish clinical proof of concept across multiple cancer types. Atransen Pharma will advance development in

collaboration with domestic and international CROs and medical institutions, with a view toward global market entry.

Locking Inhibition by APL1101

Our lead compound APL1101 shows a strong long-lasting inhibition of LAT1



Contact

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Website

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Adopted Project in FY2024

R&D Project

Research and development of a first-in-class small molecule inhibitor, for the treatment of luminal cancers

Business Operator

CORE Biomedicine Japan GK Acting CFO KAIHARA Tatsuya



Registered VC

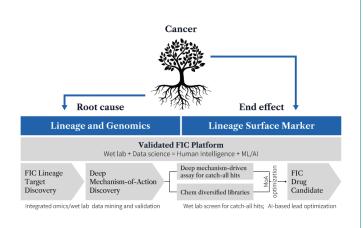
UTokyo Innovation Platform Co., Ltd.



Acting CFO
KAIHARA Tatsuya

Overview

Luminal cancers, including bladder, pancreatic, gastric, and colorectal tumors, have limited treatment options and represent a major global unmet medical need. Recent genomic studies have revealed abnormalities in a lineagespecific transcription factor, which drives tumor growth and induces resistance to immunotherapy. These alterations are estimated to affect more than 500,000 patients worldwide. To address this, we have developed CORE-1201, a selective and potent oral small-molecule inhibitor targetting this lineage transcription factor. In preclinical studies, CORE-1201 demonstrated significant tumor regression in bladder cancer PDX models and showed synergistic anti-tumor effects when combined with current standard therapies. We are currently advancing IND enabling studies and GLP/GMP manufacturing, aiming to proceed with IND submission and rapidly transition into clinical development.



Contact

https://corebiomedicine.com/#contact

Website

https://corebiomedicine.com/



R&D Project

Development of anti-FAPa CAR-T with a dual effect on tumor cells and the tumor microenvironment in GBM

R&D Principal Investigator



Head of R&D.VF NAKAMARU Kenji, Ph.D.

Business Operator

Chief Executive officer **NISHIOKA Shun**



Overview

Our core technology, the Eumbody System, enables the design of optimized CAR-T cells with enhanced cytotoxicity, proliferative capacity, and sustained efficacy through modifications of single-

chain antibodies. Currently, we are advancing research and development of FL12-CAR-T, which targets Fibroblast Activation Proteinalpha (FAPa), created using this platform.

FL12-CAR-T exhibits highly specific cytotoxicity against FAPa-expressing cells and combines the proliferative and durable characteristics conferred by the Eumbody System. FAPa expression has been reported not only in tumor cells of several cancers including glioblastoma, but also in cancerassociated fibroblasts (CAFs) that contribute to immune suppression and drug resistance.

Eliminating FAPa-expressing cells with FL12-CAR-T is expected to represent a major breakthrough in the treatment of glioblastoma and other cancers.

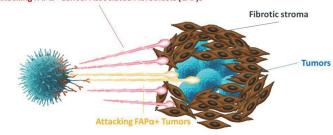
Targeting FAPα in the Tumor Microenvironment and Tumor

Registered VC

Saisei Ventures LLC

OPTF01 - A Novel Dual-Target Mechanism that Addresses Both the Tumor and Stroma

Attacking FAPa+ Cancer Associated Fibroblasts (CAF)s



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https://optieumbio.com/



Adopted Project in FY2024

R&D Project

Development of novel antibody-drug conjugate (ADC) targeting a GPCR overexpressing solid tumors

Business Operator

LiberoThera Co., Ltd. OHORI Makoto, Ph.D.



Registered VC

UTokyo Innovation Platform Co., Ltd.



Executive Director, R&D KANKE Toru, Ph.D.

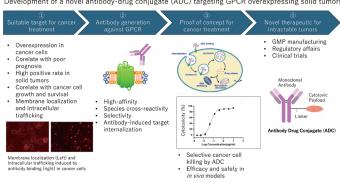
Overview

Targeting a G-protein coupled receptor (GPCR) overexpressing in solid tumors, LiberoThera is developing a first-in class novel antibody-drug conjugate (ADC) for intactable solid tumors.

GPCRs are a family of 7-transmembrane proteins which have been considered as 'Undruggable Targets' for antibody drugs due to difficulties of antibody generation. At LiberoThera, utilizing its unique antibody technologies against membrane proteins, multiple high-binding candidate antibodies against the target GPCR have been generated and evaluated their potential as ADCs for cancer treatment.

In this program, we will further evaluate and optimize the lead candidates to assess their efficacy and safety in preclinical models to determine the final clinical candidate. Subsequently, drug manufacturing and regulatory processes, such as cell line development, PK and PD studies will be followed, to proceed it to clinical trials aiming to obtain clinical POC enabling to provide a novel therapeutic for patients with intractable cancer.

Development of a novel antibody-drug conjugate (ADC) targeting GPCR overexpressing solid tumors



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https://www.liberothera.com/english/



R&D Project

Development of a Bacteriophage Cocktail ARW001 for the Treatment of Pseudomonas aeruginosa **Lung Infections**

Business Operator

Arrowsmith Inc. CEO, CScO ANDO Hiroki, PhD.

Arrowsmith >

Registered VC

JAFCO Group Co., Ltd.





CEO, CScO ANDO Hiroki, PhD

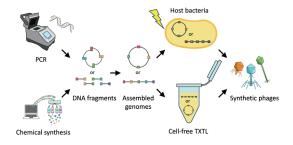
Overview

Arrowsmith Inc. is a biotech startup dedicated to realizing the potential of "phage therapy" - a novel approach to treating drug-resistant and hard-to-treat bacterial infections using bacteriophages (phages), viruses that specifically infect and kill bacteria.

Our lead program, ARW001, is a phage cocktail targeting Pseudomonas aeruginosa infections. It comprises multiple phages exhibiting a broad host range, strong lytic activity, and high stability. A key innovative feature of ARW001 is the inclusion of a genetically modified phage developed through our "Synthetic Engineering Platform" (see right figure). This enables modification of tail fibers to enhance target bacteria recognition, and allows insertion of functional genes that degrade biofilms viscous protective barriers produced by P. aeruginosa that hinder conventional treatments.

Through this AMED-supported program, we advance nonclinical,

CMC, and regulatory activities for ARW001 with a focus on enabling early clinical development in the US. Our goal is to establish ARW001's efficacy, safety, and therapeutic value, paving the way for a new class of precision antimicrobials.



Synthetic Engineering Platform: Designed phage genomes are constructed in vitro from PCRimplified or chemically synthesized DNA fragments and introduced into host bacteria or cellfree TXTL to reboot synthetic phages.

https://arrowsmith.co.jp/contact

https://arrowsmith.co.jp



Adopted Project in FY2025

R&D Project

Clinical development of bispecificity allogeneic CAR-T cell therapy for CD19/CD20 positive relapsed/refractory B-cell lymphoma

Business Operator

AvenCell Japan KK

CHIEF EXECUTIVE OFFICER, Representative Director Andrew Schiermeier, PhD



Registered VC

Eight Roads Capital Advisors Hong Kong Limited

R&D Principal Investigator



VP, Global Operations;

Markus Orchowski.

Overview

Advances in CD19-targeted autologous CAR-T cell therapy have made treatment possible for previously difficult-to-treat conditions such as relapsed and refractory lymphoma. However, many patients experience treatment resistance, leading to relapse and lack of sustained efficacy. Additionally, currently approved CAR-T therapies are autologous, posing challenges such as high development costs, prolonged time to treatment initiation, and dependence on the patient's own CD8 cell exhaustion status

Our proprietary allogenic product, AVC203, addresses these challenges of conventional therapies through three innovative technologies.

First, TruAllo™ solves the issue of sustainability in allogeneic CAR-T cell therapy by avoiding various immune rejection mechanisms.

Second, the Tandem-type dual-specificity CAR technology

addresses treatment resistance and enhances efficacy. Our product incorporates a dual-specificity CAR targeting CD19 and CD20.

Third, RevCAR™ is a platform technology that enables on/off switching of antigen recognition using a Targeting Module.

AVC203 is primarily composed of three technologies that address the challenges of conventional therapies



A platform technology that enables the on/off switching of specificity towa a third new antigen without requiring additional development of CAR-T cells This technology is expected to genera additional pipeline candidates based o AVC203 in the future

https://avencell.com/contact/

https://avencell.com/



R&D Project

Development of a CRISPR-Cas3 genome-editing cell therapy for primary immunodeficiency

R&D Principal Investigator

General Manager, Research and Development Division YOKOYAMA Kazumasa, Ph.D.

Business Operator

C4U Corporation
President and CEO
HIRAI Akimitsu



Registered VC

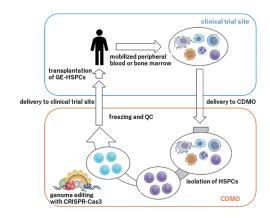
DCI Partners Co., Ltd.

Overview

Primary immunodeficiencies (PIDs) are a group of diseases caused by congenital abnormalities in parts of the immune system due to genetic mutations. This leads to a weakened ability to fight off bacteria and viruses, making patients susceptible to recurrent and severe infections. Allogeneic hematopoietic stem cell transplantation (HSCT) is a curative treatment, but because a significant number of deaths are caused by post-transplant complications like graft-versus-host disease (GvHD), there is currently no consensus on when or if this procedure should be performed.

Therefore, we have planned to develop a new treatment. This involves collecting the patient's own hematopoietic stem and progenitor cells (HSPCs), repairing the causative genetic mutations using the CRISPR-Cas3 genome editing technology, and then returning the corrected HSPCs to the patient. This innovative therapy (an ex vivo gene therapy product) would normalize the

patient's immune function to the level of a healthy person with a single, one-time treatment, without the concern of GvHD.



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Adopted Project in FY2025

R&D Project

Ferroptosis inducing anti cancer therapy

Business Operator

FerroptoCure Inc.

OTSUKI Yuji



Registered VC

ANRI Co., Ltd.



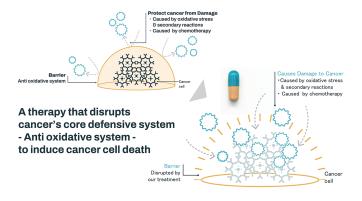


CEO OTSUKI Yuji, MD, PhD

Overview

Drug resistance remains a major challenge in cancer treatment, with many cases in which existing therapies such as chemotherapy, molecular targeted agents, and immune checkpoint inhibitors fail to achieve sufficient efficacy. In particular, in recurrent, metastatic, and refractory cancers, cancer cells often acquire mechanisms to evade cell death during treatment, and this drug resistance poses a significant barrier to improving treatment outcomes. In recent years, it has been revealed that the avoidance of ferroptosis, an iron-dependent form of cell death, is one of the causes of this resistance mechanism, drawing attention as a novel therapeutic target. FC004, the compound under development in this project, is an orally available small molecule that selectively induces ferroptosis, offering a new treatment option for cancers insufficiently addressed by conventional therapies. Preclinical studies have confirmed

both efficacy and safety, and the development will be accelerated in the areas of pharmacology, toxicology, and manufacturing, with the aim of initiating early-phase clinical trials abroad.



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Website

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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 Medical Ecosystem Development,

Department of Medical Innovation Ecosystem

Japan Agency for Medical Research and Development (AMED)





Japan Agency for Medical Research and Development

Strengthening Program for Pharmaceutical Startup Ecosystem

Division of Medical Ecosystem Development, Department of Medical Innovation Ecosystem



AMED

