AvenCell Therapeutics Announces First Patient Dosed in Phase I QUADvance Study with AVC-203, a Novel Allogeneic CD19/CD20 Dual-Targeting CAR-T Investigational Therapy for the Treatment of Relapsed/Refractory B-Cell Malignancies

AVC-203 is the world's first CRISPR-engineered allogeneic dual-targeting CD19/CD20 switchable CAR-T cell therapy to enter clinical testing

WATERTOWN, Mass., April 2, 2026 (PRNEWSWIRE) — AvenCell Therapeutics, Inc., a leading clinical-stage cell therapy company focused on advancing both switchable and allogeneic CAR-T cell therapies, today announced that it has dosed the first patient in the Phase I QUADvance study (AVC-203-01) with AVC-203 for the treatment of relapsed/refractory B-cell malignancies.

AVC-203 is a CRISPR-engineered allogeneic CAR-T candidate designed to simultaneously target and eliminate cells expressing receptors CD19 and/or CD20, which are known to be expressed in nearly all B-cell malignancies, including diffuse large B-cell lymphoma (DLBCL). The product incorporates a novel dimerized construct combining CD19/CD20 dual-targeting with AvenCell's proprietary RevCAR switchable receptor, enabling future indication flexibility and target expansion beyond CD19/CD20 through bi- or tri-specific bridging proteins.

"Patients with relapsed/refractory B-cell malignancies who have exhausted currently available treatment options, including approved autologous CAR-T therapies, have limited alternatives and a poor prognosis," said Professor Martin Wermke, Head of the Early Clinical Trial Unit at the National Cancer Center Dresden. "AvenCell's allogeneic approach, combined with its innovative dual-targeting and switchable technology, represents a promising new therapeutic strategy for these patients."

"Dosing the first patient with AVC-203 is a significant milestone for AvenCell and for the field of allogeneic cell therapy," said Andrew Schiermeier, AvenCell's President & CEO. "We are excited to build on the promising safety and activity observed in our ongoing allogeneic CAR-T clinical program in AML (AVC-201) by now entering B-cell lymphoma with what we believe to be the most scientifically compelling allogeneic technology in the industry. AvenCell remains focused on ensuring that any patient who can benefit from CAR-T therapy can receive it, through the massive scaling of supply and dramatic reductions in cost of goods."

The AVC-203 program is supported by a grant of up to $40 million from the Japan Agency for Medical Research and Development ("AMED") (Project Name: "Strengthening Program for Pharmaceutical Startup Ecosystem" R&D Project Title: "Clinical development of bispecific allogeneic CAR-T cell therapy for CD19/CD20-positive relapsed/refractory B-cell lymphoma"), underscoring the global significance of AvenCell's allogeneic CAR-T platform. The AMED grant will support the advancement of AVC-203 toward clinical development in Japan, with the goal of bringing this innovative therapy to patients across the Asia-Pacific region.

AvenCell received both FDA IND clearance and EMA approval of its Clinical Trial Application (CTA) for the QUADvance study on first submission in late 2025, enabling trial initiation at multiple sites in the US and Europe.

About AVC-203

AVC-203 is a CRISPR-engineered allogeneic CAR-T therapy incorporating four key innovations:

1. Dual antigen targeting: AVC-203 CAR-T cells contain a receptor that simultaneously targets CD19 and CD20.

2. Immune evasion: CRISPR/Cas9 engineering enables donor cells to avoid both Graft-versus-Host Disease (GvHD) and rejection by the patient's immune system.

3. Improved T-cell fitness and off-the-shelf availability: Allogeneic manufacturing from healthy donors leverages better T-cell fitness and eliminates patient-specific production, enabling immediate treatment.

4. Switchable targeting: A RevCAR receptor dimerized to the CD19/CD20 CAR enables flexible targeting of additional tumor antigens through bi- or tri-specific bridging proteins, allowing future target expansion beyond CD19/CD20.

About AVC-203 Clinical Program

The QUADvance study (AVC-203-01) is a Phase I/II trial evaluating the safety, tolerability, efficacy, and pharmacokinetics of AVC-203 in adults with relapsed or refractory B-cell malignancies. The study is being conducted at multiple sites in the US and Europe, with planned expansion to Japan. The Phase Ia dose escalation is expected to be followed by a Phase Ib dose expansion study and a Phase II pivotal trial.

About B-Cell Malignancies

B-cell malignancies — including non-Hodgkin lymphomas, multiple myeloma, and B-cell acute lymphoblastic leukemia (B-ALL) — account for the majority of blood cancers. Approximately 120,000 and 150,000 new cases are diagnosed annually in the United States and Europe, respectively. While approved autologous CAR-T therapies have demonstrated meaningful clinical activity in certain B-cell malignancies, significant challenges remain, including lengthy manufacturing timelines, high costs, and limited accessibility. Allogeneic CAR-T therapies such as AVC-203 aim to address these limitations through off-the-shelf availability, consistent product quality, and scalable manufacturing.

About AvenCell Therapeutics

AvenCell derives its name from the French word "avenir" to reflect the aim to be the FUTURE of cell therapy. AvenCell is building a truly transformative cell therapy company that targets difficult-to-treat cancers, with its lead programs focusing on acute myeloid leukemia (AML) and B-cell malignancies, and additional programs targeting other hematological malignancies, auto-immune diseases, and solid tumors. AvenCell was formed with the goal to create truly allogeneic cells that persist as long or longer than autologous therapies and develop a universal and switchable construct that allows complete control and target redirection of T cells after they are infused into a patient. Integration of these two platforms allows for complete separation of the manufacturing of cells from ultimate patient and cancer target, thus providing significant scalability potential at orders of magnitude more efficient than current approaches.

Founded in 2021 by Blackstone Life Sciences, Cellex Cell Professionals, and Intellia Therapeutics, AvenCell incorporated the clinical-stage biopharmaceutical company GEMoaB GmbH. The company is headquartered in Watertown, Massachusetts, with research, clinical and manufacturing operations in Dresden, Germany.

For more information, please visit www.avencell.com.

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Forward-Looking Statements

This press release contains "forward-looking statements" of AvenCell Therapeutics, Inc. ("AvenCell" or the "Company") within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements regarding AvenCell's beliefs and expectations regarding: the safety, efficacy, success and advancement of its clinical programs for AVC-201 and AVC-203 for the treatment of hematological malignancies pursuant to their clinical trial applications, including the initiation, enrollment, dosing and completion of clinical trials, such as planned enrollment for the Phase 1 portion of the studies for AVC-201 and AVC-203.

Forward-looking statements involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including AvenCell's ability to initiate, progress or complete pre-clinical or clinical studies within currently anticipated timelines or at all, and the possibility of unfavorable results from ongoing or additional pre-clinical or clinical studies; uncertainties relating to regulatory applications and related filing and approval timelines; risks related to AvenCell's relationships and collaborations with third parties; risks related to the maintenance and protection of AvenCell's intellectual property; risks related to the potential successful development and commercialization of AvenCell's product candidates; and risks associated with AvenCell's understanding of cell therapy and its application to the treatment of cancers.

All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The reader is cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties and is cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements are based on information currently available to AvenCell, and AvenCell assumes no obligation and disclaims any intent to update any such forward-looking statements.

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