



NEWS RELEASE

Affimed and Artiva Biotherapeutics Announce Partnership to Advance Combination Therapy of Innate Cell Engager (ICE®) AFM13 and Off-the-Shelf Allogeneic NK Cell Therapy AB-101

11/3/2022

- Companies to combine their clinical programs (AFM13, AB-101) to address high unmet need of CD30-positive lymphoma patients
- Affimed's AFM13 in combination with cord blood-derived NK cells demonstrated exceptionally high response rates in relapsed and refractory CD30-positive lymphoma patients
- AB-101 is a clinical-stage, cryopreserved, off-the shelf, non-genetically modified, allogeneic cord blood-derived NK cell manufactured at large scale via Artiva's AlloNK™ platform as a universal ADCC-enhancing cell therapy
- In preclinical studies, the combination of AFM13 and AB-101 demonstrated potent anti-tumor activity
- An investigational new drug (IND) submission to the U.S. Food and Drug Administration (FDA) is planned for the first half of 2023
- Affimed to receive 67% of the combination therapy revenues, and Artiva to receive 33%
- Conference call and webcast scheduled for November 3, 2022 at 10:30 a.m. EDT/15:30 CET

Heidelberg, Germany and San Diego, November 3, 2022 – Affimed N.V. (Nasdaq: AFMD) ("Affimed"), and Artiva Biotherapeutics Inc. ("Artiva"), both immune-oncology companies focused on developing and commercializing therapies utilizing the innate immune system, today announced a new strategic partnership to jointly develop, manufacture, and commercialize a combination therapy comprised of Affimed's Innate Cell Engager (ICE®) AFM13 and Artiva's cord blood-derived, cryopreserved off-the-shelf allogeneic NK cell product candidate, AB-101.

Affimed submitted a pre-IND meeting request for the AFM13 and AB-101 co-administered combination therapy to the FDA requesting feedback on the clinical trial design in relapsed/refractory (r/r) Hodgkin lymphoma (HL) with an exploratory arm evaluating the combination in r/r CD30-positive peripheral T-cell lymphoma (PTCL) and potential path to registration. FDA responded to this request and guided to providing feedback by Q1 2023.

This clinical agreement follows the parties' existing two-year preclinical collaboration to assess combining elements of the companies' respective platforms in the generation of targeted, off-the-shelf allogeneic NK cell therapies. As part of the collaboration, the companies evaluated the combination of AFM13 and AB101 in various preclinical models and generated data that supports development of a co-administered combination therapy.

"Based on the compelling clinical data we have generated for AFM13 in combination with NK cells, we are committed to finding the fastest path to bringing this potentially life-changing treatment to lymphoma patients," said Dr. Adi Hoess, CEO of Affimed. "The allogeneic NK field is still at a nascent stage, and we selected Artiva because of their commercially-viable production process that can support a multicenter clinical trial and potentially enable a path to registration."

"We are developing AB-101 as a universal ADCC enhancer when combined with monoclonal antibodies and NK cell engagers," said Dr. Fred Aslan, CEO of Artiva. "The data Affimed has generated to date with AFM13 in combination with cord blood-derived NK cells in a patient population with great unmet need is very compelling, and we are excited to partner with Affimed on what could become one of the first approvals for an allogeneic NK cell therapy-based regimen."

AFM13 is currently being investigated in combination with allogeneic cord blood-derived NK cells (CBNK) from The University of Texas MD Anderson Cancer Center. In this investigator sponsored study, data published earlier today for presentation at the 64th ASH Annual Meeting and Exposition demonstrated that all 24 patients in the recommended Phase 2 dose cohort responded (overall response rate of 100%) and showed a complete response rate of 70.8%. The combination was well tolerated with few infusion-related reactions and without cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, or graft versus host disease.

The Affimed-Artiva partnership aims to expedite further development of the combination therapy in CD30-positive lymphoma patients who have exhausted other treatment options. AB-101 has already completed a monotherapy safety cohort in an initial Phase 1 trial and is currently being assessed in combination with the anti-CD20 monoclonal antibody, rituximab, in patients with relapsed or refractory non-Hodgkin lymphoma (NHL). Preclinical results investigating the combination of AFM13 and AB-101 have further demonstrated enhanced anti-tumor activity. The companies plan to file an IND for the program in relapsed/refractory CD30-positive lymphoma patients during the first half of 2023.

Under the terms of the agreement, Affimed and Artiva will pursue the development of the AFM13/AB-101 combination treatment in the United States on a co-exclusive basis. Affimed will lead regulatory activities through Phase 2 and any confirmatory studies. Affimed will be responsible for funding clinical study costs through Phase 2, while Artiva will be responsible for the costs of supplying AB-101 and IL-2 for such studies. If accelerated approval is obtained, the companies will share confirmatory study costs on a 50/50 basis.

Both companies will retain commercialization and distribution rights and book sales for their respective products. Affimed will be responsible for promotional activities and expenses of the combination therapy. Pursuant to the agreement, revenues from the combination will be shared, with Affimed receiving 67% of the combination therapy revenue and Artiva receiving 33%.

CONFERENCE CALL AND WEBCAST INFORMATION

Affimed and Artiva will host a conference and webcast on November 3, 2022, at 10:30 a.m. EDT / 15:30 CEST to discuss this partnership and next steps in the development of AFM13 in combination with AB-101. The conference call will be available via phone and webcast. A live audio webcast of the conference call will be available in the “Webcasts” section on the “Investors” page of the Affimed website at <https://www.affimed.com/investors/webcasts-and-corporate-presentation/>.

To access the call by phone, please use link <https://register.vevent.com/register/BIca92c598dd7a41319b8a09f5f7ce08bf>, and you will be provided with dial in details and a pin number.

To avoid delays, we encourage participants to dial into the conference call fifteen minutes ahead of the scheduled start time.

A replay of the webcast will be accessible at the same link for 30 days following the call.

About AFM13

AFM13 is a first-in-class innate cell engager (ICE®) that uniquely activates the innate immune system to destroy CD30-positive hematologic tumors. AFM13 induces specific and selective killing of CD30-positive tumor cells, leveraging the power of the innate immune system by engaging and activating natural killer (NK) cells and macrophages. AFM13 is Affimed’s most advanced ICE® clinical program and is currently being evaluated as a monotherapy in a registration-directed trial in patients with relapsed/refractory peripheral T-cell lymphoma (REDIRECT). Additional details can be found at www.clinicaltrials.gov (NCT04101331).

About AB-101

AB-101 is a cord blood-derived, allogeneic, cryopreserved, ADCC-enhancing NK cell therapy candidate for use in combination with monoclonal antibodies or innate-cell engagers. Artiva selects cord blood units with the high affinity variant of the receptor CD16 and a KIR-B haplotype for enhanced product activity. Artiva can generate thousands of doses of pure, cryopreserved, infusion-ready NK cells from a single umbilical cord blood unit while retaining the high and consistent expression of CD16 without the need for engineering. Artiva is conducting a Phase 1/2 multicenter clinical trial (ClinicalTrials.gov Identifier: NCT04673617) to assess the safety and clinical activity of AB-101 alone and in combination with the anti-CD20 monoclonal antibody, rituximab, in patients with relapsed or refractory B-cell-non-Hodgkin lymphoma (NHL) who have progressed beyond two or more prior lines of therapy.

About Affimed N.V.

Affimed (Nasdaq: AFMD) is a clinical-stage immuno-oncology company committed to give patients back their innate ability to fight cancer by actualizing the untapped potential of the innate immune system. The company's proprietary ROCK® platform enables a tumor-targeted approach to recognize and kill a range of hematologic and solid tumors, enabling a broad pipeline of wholly-owned and partnered single agent and combination therapy programs. The ROCK® platform predictably generates customized innate cell engager (ICE®) molecules, which use patients' immune cells to destroy tumor cells. This innovative approach enabled Affimed to become the first company with a clinical-stage ICE®. Headquartered in Heidelberg, Germany, with offices in New York, NY, Affimed is led by an experienced team of biotechnology and pharmaceutical leaders united by a bold vision to stop cancer from ever derailing patients' lives. For more about the company's people, pipeline and partners, please visit: www.affimed.com.

About Artiva

Artiva's mission is to deliver highly effective, off-the-shelf, allogeneic NK cell-based therapies utilizing our Manufacturing-First approach, that are safe and accessible to cancer patients. Artiva's pipeline includes AB-101, an ADCC enhancer NK-cell therapy candidate for use in combination with monoclonal antibodies or innate-cell engagers. Artiva is currently advancing a Phase 1/2 clinical trial of AB-101 in combination with rituximab for the treatment of relapsed or refractory B-cell lymphomas. Artiva's pipeline also includes AB-201, an anti-HER2 CAR-NK cell therapy candidate for the treatment of HER2-overexpressing tumors, such as breast, gastric, and bladder cancers, and for which an IND has been allowed by FDA, and a pipeline of CAR-NK candidates targeting both solid and hematopoietic cancers. Artiva has entered into therapeutic NK cell collaborations with Merck Sharp & Dohme Corp. and with Affimed GmbH. Artiva's AlloNK™ platform incorporates cell expansion, activation, and engineering technology developed by Artiva's strategic partner, GC Cell Corporation, a member of the GC family of companies, a leading healthcare company in Korea. Artiva is headquartered in San Diego.

Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “look forward to,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions. Forward-looking statements appear in a number of places throughout this release and include statements regarding our intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, the potential of AFM13 and AB-101 and the Affimed-Artiva partnership, the value of our ROCK® platform, our ongoing and planned preclinical development and clinical trials, potential development pathways and commercial results. Actual results may differ for various reasons, including the risks, uncertainties and other factors described under the heading “Risk Factors” in Affimed’s filings with the SEC, as well as the fact that the current clinical data of AFM13 in combination with NK cell therapy is based on AFM13 in combination with allogeneic cord blood-derived NK cells from The University of Texas MD Anderson Cancer Center, as opposed to AB-101, the timing and content of FDA guidance with respect to the AFM13/AB-101 combination, the clinical and commercial viability of AB-101 and the potential for commercial revenue from the collaboration. Given these risks, uncertainties, and other factors, you should not place undue reliance on these forward-looking statements, and we assume no obligation to update these forward-looking statements, even if new information becomes available in the future.

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