



## PRESS RELEASE

### **Affimed Announces IND Clearance for a Phase 2 Clinical Trial Investigating AFM13 and AB-101 Combination Therapy**

- Phase 2 combination study of AFM13 with AB-101 in relapsed or refractory (r/r) classical Hodgkin Lymphoma (cHL) will be an open-label, multi-center, multi-cohort study with a safety run-in followed by dose optimization and expansion phase
- Primary endpoints of the study are to assess the antitumor activity by objective response rate (ORR) including complete responses (CR) and partial responses (PR)
- Secondary endpoints of the study are to assess efficacy, durability of response (DOR), safety and tolerability, and immunogenicity of the combination therapy
- The study will include an exploratory cohort of CD30-positive peripheral T-cell lymphoma (PTCL) patients
- Company to discuss investigational new drug (IND) clearance and study details on Q1 2023 earnings and business update call today at 8:30 a.m. EDT / 14:30 CET

**Heidelberg, Germany, May 23, 2023** – [Affimed N.V.](#) (Nasdaq: AFMD) (“Affimed” or the “Company”), a clinical-stage immuno-oncology company committed to giving patients back their innate ability to fight cancer, announced today that the U.S. Food and Drug Administration (FDA) has cleared its IND application for the combination of AFM13, its first-in-class tetravalent bispecific innate cell engager (ICE<sup>®</sup>) and AB-101, Artiva Biotherapeutics Inc.’s (“Artiva”) clinical-stage, cryopreserved, off-the shelf, non-genetically modified, allogeneic cord blood-derived natural killer (NK) cells to initiate the clinical trial, AFM13-203 (LuminICE-203). The phase 2 study will be an open-label, multi-center, multi-cohort study with a safety run-in followed by dose optimization and expansion phases. The study will evaluate the safety and efficacy of AFM13 in combination with AB-101 in patients with r/r cHL and CD30-positive PTCL. Affimed intends to initiate the study in the third quarter of 2023 and expects to report data from the safety run-in phase in the first half of 2024.

"We are excited to have received FDA clearance of our IND application for this promising combination therapy of AFM13 and AB-101, which has the potential to provide a new treatment option for Hodgkin Lymphoma and PTCL patients," said Wolfgang Fischer, Chief Operating Officer of Affimed. "We are very focused on getting the study up and running in the third quarter of 2023 and advancing it as quickly as possible."

“Despite recent advancements in the field that include promising targeted and immunological agents, there is still an unmet medical need for treatments in the r/r setting of classical Hodgkin

Lymphoma,” said Dr. Andreas Harstrick, Chief Medical Officer at Affimed. “Therapies like the combination of AFM13 with NK cells that enable patients to achieve complete responses have the potential to contribute to this benefit.”

AFM13-203 (LuminICE-203) will build on data generated from the Company’s AFM13-104 study together with The University of Texas MD Anderson Cancer Center, which demonstrated the promise of AFM13 in combination with cord blood-derived NK (cbNK) cells for the treatment of r/r cHL and Non-Hodgkin lymphoma patients. Data from the AFM13-104 study, presented at the American Society of Hematology (ASH) 2022, demonstrated a 94% ORR and a CR rate of 71% in 35 heavily pre-treated CD30-positive Hodgkin lymphoma (HL) and Non-Hodgkin lymphoma (NHL) patients treated at the recommended Phase 2 dose (RP2D). 63% of patients (n=24) treated at the RP2D with at least 6 months of follow-up after the initial infusion remained in CR for at least 6 months. In addition, the treatment was well tolerated with no cases of cytokine release syndrome, immune effector cell-associated neurotoxicity or graft versus host disease observed.

### **Study Details**

AFM13-203 (LuminICE-203) is a phase 2, open-label, multi-center, multi-cohort study with a safety run-in followed by dose optimization and expansion phases. Patients with a diagnosis of r/r cHL who will enroll in the study must have received at least two lines of therapy, including one prior line of combination chemotherapy. In addition, prior therapy must also have included brentuximab vedotin and a PD-1 checkpoint inhibitor.

The trial is designed to enroll up to 134 r/r cHL patients, including 24 patients in the safety run-in, and between 68 – 110 in the dose optimization and expansion phases. The study also includes an exploratory cohort comprised of an additional 20 PTCL patients.

During the IND process, Affimed requested FDA feedback on the suitability of the study to support an accelerated approval in cHL. At the recommendation of the FDA, in parallel to advancing the study, Affimed expects to have further discussions with the agency on the requirements for a registration application in the U.S.

### **Conference Call and Webcast Information**

Affimed will host a conference call and webcast on May 23, 2023, at 8:30 a.m. EDT / 14:30 CET to discuss first quarter 2023 financial results and corporate developments.

The conference call will be available via phone and webcast. The live audio webcast of the 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/Bled97601353374e7a9d7a85f39e91f238>, and you will be provided with dial-in details and a pin number.

**Note:** To avoid delays, we encourage participants to dial into the conference call 15 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 Classical Hodgkin Lymphoma**

cHL is the most common CD30-positive lymphoma. cHL mainly results from the clonal transformation of cells of B-cell origin, giving rise to pathogenic Reed-Sternberg cells (RSCs). RSCs are most likely derived from germinal center B-cells that acquire unfavorable immunoglobulin V gene mutations and normally would undergo apoptosis. The characteristic large, often binucleated RSCs are mixed with a cell infiltrate composed of variable proportions of lymphocytes, histiocytes, eosinophils, and plasma cells. Based on the mix of different cells in the histological assessment, four types of cHL are described: nodular sclerosing, mixed cellularity, lymphocyte rich and lymphocyte depleted.

### **About AFM13**

AFM13 is a first-in-class tetravalent bispecific innate cell engager (ICE<sup>®</sup>) 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<sup>®</sup> clinical program and was evaluated as monotherapy in a phase 2 trial in patients with relapsed/refractory peripheral T-cell lymphoma (REDIRECT, NCT04101331).

In addition, The University of Texas MD Anderson Cancer Center is studying AFM13 in an investigator-sponsored Phase 1 trial in combination with cord blood-derived allogeneic NK cells in patients with recurrent or refractory CD30-positive lymphomas (NCT04074746). The company reported data from this study at ASH 2022 annual meeting. To find out more about AFM13 and the studies, please visit: [www.affimed.com](http://www.affimed.com).

### **About AB-101**

AB-101 is Artiva's non-genetically modified, cord blood-derived, allogeneic, cryopreserved, ADCC-enhancing NK cell therapy candidate for use in combination with monoclonal antibodies or innate-cell engagers in the out-patient setting. Artiva selects cord blood units with the high affinity variant of the receptor CD16 and a KIR-B haplotype for enhanced product activity. Using Artiva's AlloNK<sup>®</sup> platform, Artiva can generate thousands of doses of pure, cryopreserved, infusion-ready NK cells from a single umbilical cord blood unit while retaining high and consistent expression of CD16 and other tumor-engaging receptors, 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 (B-NHL) who have progressed beyond two or more prior lines of therapy. This study is progressing at multiple clinical sites across the U.S., and AB-101 is administered weekly in the out-patient setting over one-month cycles and with up to four cycles to assess therapeutic efficacy and durability. Artiva will present data from the first-in-

human phase 1/2 clinical trial of AB-101 in combination with rituximab in R/R non-Hodgkin lymphoma at the 2023 American Society of Clinical Oncology Annual Meeting.

### **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<sup>®</sup> 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<sup>®</sup> platform predictably generates customized innate cell engager (ICE<sup>®</sup>) 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<sup>®</sup>. 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](http://www.affimed.com).

### **About Artiva**

Artiva's mission is to deliver highly effective, off-the-shelf, allogeneic NK cell-based therapies utilizing its 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<sup>®</sup> 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 South Korea. Artiva is headquartered in San Diego. For more information, please visit [www.artivabio.com](http://www.artivabio.com).

### **Forward-Looking Statement**

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 the Company's intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, the potential of AFM13, AFM24, AFM28 and the Company's other product candidates, the value of its ROCK<sup>®</sup> platform, its ongoing and planned preclinical development and clinical trials, its collaborations and development of its products in combination with other therapies, the timing of and its ability to make regulatory filings and obtain and maintain regulatory approvals for its product candidates, its intellectual

property position, its collaboration activities, its ability to develop commercial functions, clinical trial data, its results of operations, cash needs, financial condition, liquidity, prospects, future transactions, growth and strategies, the industry in which it operates, the macroeconomic trends that may affect the industry or the Company, such as the instability in the banking sector experienced in the first quarter of 2023, impacts of the COVID-19 pandemic, the benefits to Affimed of orphan drug designation, the impact on its business by political events, war, terrorism, business interruptions and other geopolitical events and uncertainties, such as the Russia-Ukraine conflict, the fact that the current clinical data of AFM13 in combination with NK cell therapy is based on AFM13 precomplexed with fresh allogeneic cord blood-derived NK cells from The University of Texas MD Anderson Cancer Center, as opposed to Artiva's AB-101 and other uncertainties and factors described under the heading "Risk Factors" in Affimed's filings with the SEC. Given these risks, uncertainties, and other factors, you should not place undue reliance on these forward-looking statements, and the Company assumes no obligation to update these forward-looking statements, even if new information becomes available in the future.

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