



## PRESS RELEASE

### **Affimed Announces Oral Presentation of Phase 1/2 Data from AFM13 in Combination with Allogeneic NK Cells at the 2023 ASH Annual Meeting**

- In 36 patients with CD30-positive lymphoma treated at the recommended Phase 2 dose level (RP2D), the combination treatment of AFM13 with allogeneic NK cells shows a 94.4% objective response rate and a 72.2% complete response rate as of the July 2023 cut-off date for data included in the abstract
- Patients were heavily pretreated (median of 7 prior lines) and refractory to their most recent line of therapy
- Patients received up to four cycles and the treatment was well tolerated
- Updated clinical results including data on event free survival and overall survival with a later cut-off date will be given in an oral presentation on Monday, December 11, 2023 at 11:45 a.m. Pacific Standard Time (PST)

**Mannheim, Germany, November 2, 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, today announced two upcoming presentations on its lead innate cell engager (ICE®) AFM13 at the American Society of Hematology (ASH) 2023 Annual Meeting.

In the first presentation, Yago Nieto, M.D., Ph.D., Professor of Stem Cell Transplantation and Cellular Therapy at The University of Texas MD Anderson Cancer Center and principal investigator of the study, will present the updated results from the AFM13-104 phase 1/2 trial evaluating AFM13 in combination with cord blood-derived natural killer (cbNK) in patients with CD30-positive relapsed or refractory (r/r) Hodgkin and non-Hodgkin lymphomas in an oral presentation, on Monday, December 11, 2023 at 11:45 a.m. PST / 2:45 p.m. EST.

A total of 42 patients were enrolled in the study with 36 patients treated at the RP2D. All patients were heavily pretreated and refractory to their most recent line of therapy with active progressive disease at the time of enrollment. As of the July 2023 cut-off date for data presented in the abstract, the treatment regimen achieved an objective response rate (ORR) of 94.4% with a complete response rate of 72.2% in the patients treated at the RP2D. In addition, the treatment regimen demonstrated a good safety and tolerability profile with no cases of cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS) or graft versus host disease (GVHD) of any grade.

Across all dose levels as of the cutoff date, median event free survival (EFS) and overall survival (OS) were 8 months and not reached, respectively. A more in-depth analysis of the data and updated EFS/OS data using a later cut-off date will be presented during Dr. Nieto's oral presentation.

The second presentation will be a poster featuring the design of Affimed's phase 2 LuminICE-203 clinical trial investigating AFM13 in combination with Artiva's AlloNK<sup>®</sup> (also known as AB-101), an allogeneic, non-genetically modified NK cell therapy candidate. The open-label, multi-center, multi-cohort study (NCT05883449) study is based on the unprecedented results achieved in the investigational AFM13-104 study and will evaluate the efficacy and safety of the combination in patients with r/r HL and certain r/r CD30+ PTCL subtypes. Affimed has recently received [Fast-track designation](#) for the AFM13/AB-101 combination.

"AFM13 in combination with allogeneic NK cells has shown impressive activity with a good tolerability and safety profile demonstrating the potential of this therapy for relapsed/refractory CD30-positive lymphoma patients that have exhausted all options," said Dr. Andreas Harstrick, Chief Medical Officer at Affimed. "We are confident that the phase 2 LuminICE-203 study will allow us to build on the outstanding results we have seen in the AFM13-104 trial and look forward to providing updates as the study progresses."

#### **Details of AFM13 Oral Presentation and Abstract**

**Title:** Innate Cell Engager (ICE<sup>®</sup>) AFM13 Combined with Preactivated and Expanded (P+E) Cord Blood (CB)-Derived Natural Killer (NK) Cells for Patients with Refractory CD30-Positive Lymphomas: Final Results

**Session:** Cellular Immunotherapies: Early Phase and Investigational Therapies: Novel Approaches to Enhance Cellular Therapies and Immune Responses in Leukemias and Lymphomas

**Date & Time:** Monday, December 11, 2023 at 11:45 a.m. PST

**Location:** San Diego Convention Center, Room 6CF

#### **Details of LuminICE-203 Poster Presentation**

**Title:** AFM13 in Combination with Allogeneic Natural Killer Cells (AB-101) in Relapsed or Refractory Hodgkin Lymphoma and CD30<sup>+</sup> Peripheral T-Cell Lymphoma: A Phase 2 Study (LuminICE)

**Session:** Cellular Immunotherapies: Early Phase and Investigational Therapies: Poster III

**Session Date & Time:** Monday, December 11, 2023 from 6:00 p.m. - 8:00 p.m. PST

**Location:** San Diego Convention Center, Halls G-H

The full abstracts for both presentations are available on the ASH conference website via the following link: [65th ASH Annual Meeting & Exposition - Hematology.org](https://www.asconline.org/2023/Program/Abstracts/Abstracts-Home.aspx)

#### **About the AFM13-104 Phase 1/2 Study**

The University of Texas MD Anderson Cancer Center is studying AFM13 in an investigator-sponsored phase 1/2 trial in combination with cord blood-derived allogeneic NK cells in patients with recurrent or

refractory CD30-positive lymphomas. The study is a dose-escalation trial of precomplexed NK cells, followed by an expansion phase, recruiting up to 40 patients with r/r CD30 positive lymphomas, treated with the RP2D of  $1 \times 10^8$  NK cells/kg followed by three weekly doses of 200 mg AFM13 monotherapy. Each treatment cycle consists of lymphodepleting chemotherapy with fludarabine (30 mg/m<sup>2</sup> per day) and cyclophosphamide (300 mg/m<sup>2</sup> per day) followed two days later by a single infusion of cytokine-preactivated and expanded cord blood-derived NK cells that are pre-complexed with AFM13. Three weekly infusions of AFM13 (200 mg) monotherapy are subsequently administered and responses are assessed by the investigator on day 28 by FDG-PET.

MD Anderson has an institutional financial conflict of interest with Affimed related to this research and has therefore implemented an Institutional Conflict of Interest Management and Monitoring Plan. Additional information about the study can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT04074746).

### **About AFM13**

AFM13 is a first-in-class 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 a tetravalent bispecific innate cell engager designed to act as a bridge between the innate immune cells and the tumor creating the necessary proximity for the innate immune cells to specifically destroy the tumor cells.

### **About Affimed N.V.**

Affimed (Nasdaq: AFMD) is a clinical-stage immuno-oncology company committed to giving 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 Mannheim, 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 AlloNK<sup>®</sup> and Artiva**

Artiva is an immunotherapy company with the ability to produce off-the-shelf, allogeneic NK cell therapies at a massive scale. Artiva's mission is to develop effective, safe and accessible cell therapies for patients with devastating autoimmune diseases and cancers. Artiva's lead program, AlloNK<sup>®</sup> (also known as AB-101), is an allogenic, non-genetically modified NK cell therapy candidate designed to enhance the antibody-dependent cellular cytotoxicity (ADCC) effect of monoclonal antibodies or NK cell engagers. AlloNK is a cryopreserved, off-the-shelf therapy with the potential to be administered in the community setting. Using the company's cell therapy manufacturing platform, Artiva can generate thousands of doses of cryopreserved, infusion-ready AlloNK cells from a single umbilical cord blood unit while retaining high and consistent expression of CD16 and other activating NK receptors. Artiva is headquartered in San Diego. For more information, visit [www.artivabio.com](http://www.artivabio.com).

## **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 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® 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 AlloNK® 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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