



## PRESS RELEASE

### Affimed Presents Updated Data for AFM28 Demonstrating Efficient Elimination of Leukemic Stem and Progenitor Cells in Combination with Allogeneic NK cells in Preclinical Models of Acute Myeloid Leukemia and Myelodysplastic Syndrome at the Annual ASH 2022 Meeting

- AFM28 efficiently directs allogeneic NK cells to CD123-positive leukemic cells, including leukemic stem and progenitor cells, inducing their depletion in samples of patients with Acute Myeloid Leukemia (AML) and myelodysplastic syndrome (MDS)
- Leukemia cell lysis was independent of differences in CD123 expression levels and mutational status suggesting broad activity of AFM28-redirected NK cells and the potential for deep anti-leukemic responses
- These data provide further rationale for clinical evaluation of AFM28 both as monotherapy and in combination with adoptive NK cell therapy

**Heidelberg, Germany, December 12, 2022** – 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 presented a poster highlighting new preclinical data for its Innate Cell Engager (ICE®) AFM28 targeting CD123 and CD16A at the 64<sup>th</sup> American Society of Hematology (ASH) Annual Meeting and Exposition in New Orleans, Louisiana.

The data demonstrated the ability of AFM28 to effectively redirect allogeneic NK cells and induce depletion of CD123-positive leukemic blasts and leukemic stem cells in *ex vivo* patient samples, underscoring its potential as a novel therapeutic agent in AML. AFM28 is a novel ICE® in development for treatment of patients with myeloid diseases that have undergone multiple prior treatments and have relapsed or are refractory (R/R) to standard of care. It is designed to bind to natural killer (NK) cells and CD123-positive tumor cells to induce tumor cell killing. To date, the program has shown strong anti-tumor activity *in vivo* while maintaining a good safety profile.

“The evidence for AFM28’s ability to deplete leukemic stem and progenitor cells through allogeneic NK cells encourages us in our development path and provides hope that AFM28 could be a novel treatment option to induce long-term remissions in refractory AML patients”, said Dr. Arndt Schottelius, Chief Scientific Officer at Affimed. “We plan to initiate our first in-human study in the first half of 2023.”

AML is a difficult-to-treat disease with low cure rates and significant toxicities associated with available therapies. There is an urgent need for new approaches that are effective, provide long-term, relapse-free survival and are better tolerated.

AFM28 holds promise as a novel safe and effective therapeutic that could address the needs of underserved patients with AML.

The poster presented at ASH featured detailed preclinical evaluations further characterizing AFM28 and its mechanisms of action in models of AML. The data confirmed a concentration-dependent, NK cell-mediated lysis of CD123-positive target cells in different tumor lines, irrespective of low CD123 expression or mutational status. In addition, high CD64 expression, which negatively affects antibody-dependent cellular cytotoxicity (ADCC) of conventional and Fc-enhanced anti-CD123 antibodies, did not affect AFM28 efficacy.

A critical factor for long-term remission in AML patients is the efficient and safe depletion of leukemic blasts and corresponding stem cells. In *ex vivo* AML and MDS bone marrow samples, AFM28 induced the depletion of CD123-positive leukemia stem cells and leukemic progenitor cells while sparing healthy cells, suggesting the ability to induce deep, anti-tumor responses without irreversible bone marrow suppression. The ICE also showed inhibition of tumor growth in murine AML models, underscoring the anti-tumor activity of the program.

Affimed remains on track to initiate clinical development of AFM28 with a first-in-human phase 1 monotherapy trial in adult patients with R/R AML in the first half of 2023. In addition, Affimed plans to investigate AFM28 in combination with allogeneic NK cell therapy after a safe starting dose has been determined.

The full poster is accessible through the following link:

<https://affimed.com/affimed-science-technology/publications-and-posters/>

#### **Poster details:**

**Title:** The Novel Bispecific Innate Cell Engager (ICE®) AFM28 Efficiently Directs Allogeneic NK Cells to CD123-positive leukemic cells

**Session:** Molecular Pharmacology and Drug Resistance: Myeloid Neoplasms: Poster III

**Presentation Date & Time:** Monday, December 12, 2022, 6:00 - 8:00 p.m. CST

**Location:** Ernest N. Morial Convention Center, Hall D

## **About AFM28**

AFM28, a tetravalent, bispecific CD123- and CD16A-binding Innate Cell Engager (ICE®) developed on Affimed's Redirected Optimized Cell Killing (ROCK®) platform, is designed to bring a new immunotherapeutic approach to patients with CD123+ myeloid malignancies, including acute myeloid leukemia and myelodysplastic syndrome. It engages natural killer (NK) cells to initiate tumor cell killing via antibody-dependent cellular cytotoxicity, even at low CD123 expression levels. Clinical development is planned as both monotherapy and in combination with allogeneic NK cells in patients with relapsed/refractory CD123+ leukemias.

## **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 Redirected Optimized Cell Killing (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](http://www.affimed.com).

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