



## PRESS RELEASE

### **Affimed Presents Preclinical Data of Novel Innate Cell Engager AFM28 at the Annual Meeting of the European Hematology Association (EHA)**

- AFM28 induced potent, effective, and specific anti-tumor activity against CD123-positive cells irrespective of mutational status
- Study demonstrated specific anti-tumor response even at low levels of CD123 expression with no evidence for off-target cytotoxic activity towards CD123-negative healthy bone marrow progenitors
- *In vivo* studies of an AML murine model demonstrated anti-tumor efficacy; cynomolgus toxicology models showed pharmacodynamic activity with a well-tolerated safety profile suggesting a low risk of cytokine release
- First-in-human phase 1 clinical trial of AFM28 monotherapy expected to begin in 2H 2022

**Heidelberg, Germany, June 10, 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 at the Annual Meeting of the European Hematology Association (EHA) in Vienna, Austria. The data demonstrate the cytotoxic potential of the CD123/CD16A-targeting bispecific innate cell engager (ICE®) AFM28 which is in development as a novel treatment for patients with myeloid diseases, e. g. relapsed/refractory (R/R) acute myeloid leukemia (AML). AFM28 binds to natural killer (NK) cells and CD123-positive tumor cells and demonstrated the induction of tumor cell killing *in vitro* and a good tolerability and strong anti-tumor activity *in vivo*.

“It is widely acknowledged that targeting CD123 holds significant untapped promise in developing better AML therapies. We believe our differentiated approach in targeting CD123 has the potential to provide a novel, innate immune system-engaging therapy to improve clinical outcomes,” said Dr. Arndt Schottelius, Chief Scientific Officer at Affimed. “Following these encouraging pre-clinical proof-of-concept data and the experience we have gained from our AFM13 studies so far, we will be launching a first-in-human clinical study to investigate the compound’s safety, efficacy and biological activity as monotherapy later this year and in combination with adoptive NK cells soon after.”

The data presented at EHA today provide validation of the mechanism of action (MoA) as well as preclinical proof-of-concept for AFM28 in a range of *in vitro* and *in vivo* assays. AFM28 exhibited

high-affinity binding to CD16A expressed on NK cells and high avidity conferring long cell surface retention in comparison to Fc-enhanced anti-CD123 antibody. Moreover, AFM28 demonstrated the ability to destroy CD123-positive tumor cell lines and primary leukemic cells via antibody-dependent cell-mediated cytotoxicity (ADCC).

Importantly, AFM28 was active irrespective of mutational status of tumor cells and also induced depletion when CD123 expression was very low. Strikingly, AFM28 was also active against cells not killed by an Fc-enhanced CD123-targeting comparator antibody suggesting the potential for improved clinical effectiveness. Moreover, AFM28 also depleted leukemic cells from patient bone marrow without destroying CD34-positive/CD123-negative cells, suggesting sparing of hematopoietic stem and progenitor cells.

*In vivo* studies in an AML murine model demonstrated anti-tumor efficacy, and cynomolgus toxicology models predicted pharmacodynamic activity with a well-tolerated safety profile and low risk of cytokine release syndrome.

Efficient depletion of leukemic blasts and leukemic stem cells is critical for inducing long-term remission in AML patients. As both cell types express CD123, AFM28's ability to redirect NK cells to this target killing both leukemic blasts and leukemic stem cells makes this an attractive treatment strategy. Currently, there are no curative immunotherapies available, the only option is allogenic hematopoietic stem cell transplantation (allo-HSCT).

Affimed plans to initiate clinical development of AFM28 with a first-in-human phase 1 monotherapy trial in adult patients with R/R AML in the second half of 2022. 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: [Publications and Posters - Affimed](#)

**Poster details:**

**Title:** Novel bispecific innate cell engager AFM28 for the treatment of CD123-positive acute myeloid leukemia and myelodysplastic syndrome

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**Final abstract code:** P482

**Session date and time:** Poster session on Friday, June 10<sup>th</sup>, 10:30 – 11:45 a.m. EDT / 16:30 - 17:45 CEST

## **About AFM28**

AFM28, a tetravalent, bispecific CD123- and CD16A-binding ICE<sup>®</sup> developed on Affimed's ROCK<sup>®</sup> platform, is designed to bring a new immunotherapeutic treatment to patients with CD123+ myeloid malignancies, including acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). It engages NK cells to initiate tumor cell killing via antibody-dependent cellular cytotoxicity (ADCC), 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-positive leukemias.

## **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).

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