



PRESS RELEASE

Affimed Announces Publication of Preclinical Data in *Clinical Cancer Research* Supporting Therapeutic Potential of AFM13 in Combination with Natural Killer Cells

- AFM13 in combination with natural killer (NK) cells demonstrated improved tumor recognition and enhanced tumor cell killing in vitro and in vivo.
- Preclinical data from this publication supported the Investigational New Drug (IND) application for the ongoing Phase I clinical study of AFM13 pre-complexed with NK cells.

Heidelberg, Germany, May 13, 2021 – Affimed N.V. (Nasdaq: AFMD), a clinical-stage immunoncology company committed to giving patients back their innate ability to fight cancer, announced today the publication of preclinical in vitro and in vivo research of its lead innate cell engager (ICE®), AFM13 (CD16A/CD30), combined with healthy donor-derived NK cells in [Clinical Cancer Research](#). The preclinical data demonstrated that AFM13 strongly binds to NK cells, including cytokine-activated or cord blood-derived NK (cbNK) cells, resulting in enhanced tumor recognition and antibody-dependent cellular cytotoxicity (ADCC). The research was generated through a collaboration with The University of Texas MD Anderson Cancer Center and Washington University School of Medicine and supports use of AFM13 combined with NK cells as a promising therapy for CD30-positive hematological malignancies.

“Our ROCK® platform forms the basis to generate ICE® molecules which have the ability to strongly and durably bind to CD16A on NK cells, resulting in unique antitumor properties,” said Arndt Schottelius, M.D., Ph.D., Chief Scientific Officer of Affimed. “As demonstrated by the recent presentation of initial Phase 1 data at the American Association for Cancer Research (AACR) Annual Meeting 2021 – which showed an emerging profile that appears to have the potential to provide meaningful benefit with a safety profile consistent with previous AFM13 data – pre-complexing AFM13 with NK cells presents an innovative and promising therapeutic approach for patients with impaired NK cell activity.”

“This study provided new insights into how ICE® molecules such as AFM13 may be impacted by NK cell receptor ligand alterations using multidimensional mass cytometry,” said Todd Fehniger, M.D., Ph.D., Professor of Medicine, Oncology Division, at Washington University. “Further, blood NK cells primed and differentiated into memory NK cells exhibit potent responses to CD30+ cancer cells when directed by AFM13, providing further evidence for their powerful CD16-triggered cytokine production and killing.”

Additional key findings from the research are outlined below:



- AFM13 combined with donor NK cells, including conventional NK cells from healthy donors, cytokine-induced memory-like NK cells from peripheral blood and preactivated and expanded cbNK cells, enhanced tumor cell killing compared to NK cells alone.
- When combined with AFM13, Hodgkin lymphoma patient-derived NK cells do not reach the same level of cytotoxicity compared to healthy donor-derived NK cells in vitro.
- AFM13-directed tumor cell killing was enhanced when combined with cytokine (IL-12, IL-15 and IL-18) preactivated cbNK cells compared to non-cytokine preactivated cbNK cells.
- Cytokine preactivated cbNK cells express different markers when compared to noncytokine preactivated cbNK cells, potentially accounting for superior cytotoxicity which is further enhanced with AFM13.

“This preclinical study confirmed the synergy between the cbNK cell platform developed at MD Anderson and AFM13 as a precomplexed product and provided the rationale to test this novel NK cell-based adoptive immunotherapy strategy for patients with relapsed/refractory CD30+ malignancies,” said Katy Rezvani, M.D., Ph.D., Professor of Stem Cell Transplantation and Cellular Therapy at MD Anderson.

The preclinical data published in *Clinical Cancer Research* supported the Investigational New Drug (IND) application for the ongoing Phase I clinical study of AFM13 precomplexed with cytokine-activated cbNK cells followed by AFM13 monotherapy in patients with CD30-positivemalignancies. Results of the [Phase 1 study](#) as of March 31, 2021, demonstrated an objective response rate of 100% (ORR=4/4; PR=2/4; CR=2/4) among the first patients enrolled who were all heavily pretreated. There were no observed events of cytokine release syndrome, neurotoxicity, or graft-versus-host disease. The study will progress to the higher dose cohorts with additional updates expected throughout this year.

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 or transformed mycosis fungoides (REDIRECT). The study is actively recruiting, and additional details can be found at www.clinicaltrials.gov (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. The study is a dose-escalation trial of precomplexed NK cells, with patients receiving 1×10^6 NK cells/kg in Cohort 1, 1×10^7 NK cells/kg in Cohort 2, and 1×10^8 NK cells/kg in Cohort 3. The trial is designed to explore safety and activity and determine the recommended Phase 2 dose. In each cohort, the dose of the precomplexed NK cells with AFM13 is to be followed by weekly doses of 200 mg AFM13 monotherapy for three weeks, with each patient evaluated for dose-limiting toxicities and responses on day 28.

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 (NCT04074746).

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[®] 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, New York, 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.

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, including with cbNK cells, the value of our ROCK[®] platform, our ongoing and planned preclinical development and clinical trials, our collaborations and development of our products in combination with



other therapies, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, our intellectual property position, our collaboration activities, our ability to develop commercial functions, clinical trial data, our results of operations, cash needs, financial condition, liquidity, prospects, future transactions, growth and strategies, the industry in which we operate, the trends that may affect the industry or us, impacts of the COVID-19 pandemic, the benefits to Affimed of orphan drug designation, and the risks, uncertainties and other factors described under the heading “Risk Factors” in Affimed’s filings with the Securities and Exchange Commission. 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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