



## PRESS RELEASE

### **Affimed Announces Presentation at AACR Highlighting Initial Data from Phase 1 Study of Cord Blood-derived Natural Killer Cells Pre-complexed with Innate Cell Engager AFM13**

- All four patients experienced significant disease reduction, with two complete responses and two partial responses as assessed by the investigator, with an objective response rate of 100%
- There were no observed events of cytokine release syndrome, neurotoxicity syndrome or graft-versus-host disease
- Study is continuing enrollment of the second dose cohort
- Company to host conference call/webcast on April 14 at 4:05 p.m. EDT

**Heidelberg, Germany, April 9, 2021** – Affimed N.V. (Nasdaq: AFMD), a clinical-stage immunoncology company committed to giving patients back their innate ability to fight cancer, announced today positive initial clinical data from an investigator-sponsored study at The University of Texas MD Anderson Cancer Center evaluating cord blood-derived natural killer (cbNK) cells pre-complexed with Affimed’s innate cell engager (ICE®) AFM13 (CD16A/CD30).

This approach was developed in the laboratory of Katy Rezvani, M.D., Ph.D., Professor of Stem Cell Transplantation and Cellular Therapy at MD Anderson, who is presenting the data as part of the Major Symposia and Advances sessions at the virtual American Association for Cancer Research (AACR) Annual Meeting. The presentation is available for viewing by registered participants through June 21, 2021. Dr. Rezvani will take part in a live panel discussion as part of the presentation on April 13, 2021 at 1:30 p.m. EDT.

“We are encouraged by the initial safety and efficacy data from this groundbreaking first in-human study. The finding of an objective response rate of 100% amongst our first four patients enrolled is impressive,” said Andreas Harstrick, M.D., Chief Medical Officer of Affimed. “These initial results indicate AFM13 may have the potential to help NK cells target and destroy cancer cells. We plan to continue to develop and customize approaches that leverage the unique and differentiating features of our ICE® molecules in combination with adoptive NK cell transfer to provide options for treating a variety of hematologic and solid tumors.”

The open-label, non-randomized, single-center, dose-escalation trial is evaluating the pre-complexing of AFM13 with cbNK cells followed by three weekly infusions of AFM13 monotherapy in adult patients with recurrent/refractory CD30-positive lymphomas. The trial is led by Yago Nieto, M.D., Ph.D., Professor of Stem Cell Transplantation and Cellular Therapy at MD Anderson.

“There remains a high unmet need for effective treatments in relapsed/refractory (R/R) CD30+ lymphomas. We are encouraged by the data generated from the first patients treated with



cbNK cells pre-complexed with AFM13,” said Dr. Rezvani. “The results suggest this combination is facilitating clinical responses with minimal toxicity, warranting further study as we continue to explore novel cell therapies for our patients.”

As of March 31, 2021, three patients have been dosed with two cycles of therapy in dose cohort 1 ( $1 \times 10^6$  AFM13-cbNK/kg) and one patient has received a single cycle of therapy in dose cohort 2 ( $1 \times 10^7$  AFM13-cbNK/kg). The study is currently enrolling patients in the second dose cohort of NK cells, and further updates are expected later in 2021. Results from the first cycle of the first dose cohort are being presented by Dr. Rezvani at AACR, and Affimed is supplementing the data with best responses as of March 31, 2021, as summarized below.

Patient number	cbNK Cell Dose	Patient	Cancer Type	Prior Treatment	CRS/ Neurotoxicity / GVHD	Best Response
Cohort 1 – completed						
#1	$1 \times 10^6$ / kg	43-year-old-male	Hodgkin lymphoma	4 lines of therapy (ABVD, ICE, brentuximab vedotin, nivolumab + ruxolitinib)	None	Partial response
#2	$1 \times 10^6$ / kg	31-year-old-male	Hodgkin lymphoma	14 lines of therapy (ABVD, brentuximab vedotin, HDACi/P13Ki, pembrolizumab, nivolumab, allo-HSCT, hypercytoxan, ibrutinib, niraparib, bendamustine, everolimus)	None	Partial response
#3	$1 \times 10^6$ / kg	53-year-old-female	Hodgkin lymphoma	5 lines of therapy (ABVD, ICE, brentuximab vedotin, nivolumab, GemOx)	None	Complete response after cycle 2
Cohort 2 – ongoing (1 of 3 patients enrolled)						
#4	$1 \times 10^7$ / kg	26-year-old-male	Hodgkin lymphoma	9 lines of therapy (ABVD, ICE + brentuximab vedotin, radiation, nivolumab, CD30-CART, TTI-622, brentuximab vedotin + bendamustine, allo-HSCT, brentuximab vedotin + bendamustine with brentuximab vedotin maintenance)	None	Complete response

ABVD = Adriamycin (doxorubicin), Bleomycin, Vinblastine, Dacarbazine (DTIC)

ICE = chemotherapy combination includes the drugs: ifosfamide, carboplatin, & etoposide phosphate

GemOx= gemcitabine, oxaliplatin

There were no observed events of cytokine release syndrome, neurotoxicity syndrome or graft-versus-host disease.

Response evaluation followed the Lymphoma Response to Immunomodulatory Therapy Criteria (LYRIC). All four patients had relapsed/refractory Hodgkin Lymphoma and were heavily pretreated, with between 4 and 14 previous lines of therapy which in all cases included brentuximab vedotin (Adcetris®) and anti-PD1 antibodies. Of note, patient #4 had also previously received a CD30-CAR-T.

### Conference Call/Webcast Details

Affimed will host a conference call and webcast on April 14, 2021, at 4:05 p.m. EDT to discuss the initial study findings. The conference call will be available via phone and webcast. To access the call, please dial +1 (646) 741-3167 for U.S. callers, or +44 (0) 2071 928338 for international callers, and reference passcode 1788338 approximately 15 minutes prior to the call.



A live audio webcast of the conference call will be available in the “Webcasts” section on the “Investors” page of the Affimed website at [https://www.affimed.com/investors/webcasts\\_cp/](https://www.affimed.com/investors/webcasts_cp/). A replay of the webcast will be accessible at the same link for 30 days following the call.

### **About the Phase 1 Study**

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 pre-complexed NK cells, with patients receiving  $1 \times 10^6$  NK cells/kg in Cohort 1;  $1 \times 10^7$  NK cells/kg in Cohort 2; and,  $1 \times 10^8$  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 pre-complexed 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](http://www.clinicaltrials.gov) (NCT04074746).

### **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](http://www.clinicaltrials.gov) (NCT04101331).

### **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](http://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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