



PRESS RELEASE

Affimed Presents Updated Clinical Data from Phase 1/2 Study of AFM13 Precomplexed with Cord Blood-Derived NK Cells at AACR Annual Meeting

- 100% objective response rate and improvement in the rate of complete responses (CR) from 38% to 62% after a second cycle in 13 patients treated at the recommended phase 2 dose (RP2D)
- Patients enrolled were multi-refractory with a median of seven prior lines of treatment; all Hodgkin Lymphoma patients had failed brentuximab vedotin and PD-1 therapy in addition to failing multiple lines of chemotherapy
- Of the eight patients who achieved a CR at the RP2D, seven remain in CR at median follow-up of 6.5 months, including 2 patients who remain in response after 10 months and two who received a consolidation autologous stem cell transplant (SCT)
- Treatment was well tolerated; no instances of cytokine release syndrome, immune effector cell-associated neurotoxicity or graft versus host disease were observed
- Data to be presented by Dr. Yago Nieto of The University of Texas MD Anderson Cancer Center, principal investigator of the study, as an oral presentation at AACR today, April 10, 1:00-3:00 p.m. CST during the Clinical Plenary Session

Heidelberg, Germany, April 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 provided a data update from the ongoing study of the Company’s lead innate cell engager (ICE®) AFM13 precomplexed with cord blood-derived natural killer (cbNK) cells. AFM13 is currently being investigated at The University of Texas MD Anderson Cancer Center in a [phase 1/2 study](#) in patients with CD30-positive relapsed or refractory Hodgkin and non-Hodgkin lymphomas. The investigator-sponsored study is led by Yago Nieto, M.D., Ph.D., professor of Stem Cell Transplantation and Cellular Therapy at MD Anderson. The study shows a 100% objective response rate (ORR) and an improvement of complete response (CR) rate to 62% at the recommended phase 2 dose (RP2D) in 13 patients after 2 cycles of therapy. The results will be presented today during the Clinical Plenary Session on cellular immunotherapies at the American Association for Cancer Research (AACR) Annual Meeting 2022 and will also be covered during an AACR press conference this morning.

“The data that we report today are highly encouraging. All patients on this trial were refractory to all available treatment options. Still the combination of AFM13 and precomplexed NK cells resulted in a 100% response rate and a 62% rate of complete responses. We are excited to see a deepening of responses from partial responses to complete responses with a second cycle and have amended the study to allow patients to receive additional cycles, which may further increase the efficacy,” said Dr Andreas Harstrick, Chief Medical Officer at Affimed. “To our knowledge, this is the highest response rate reported so far in Hodgkin Lymphoma patients with treatment refractory disease.”

As of the cut-off date, the study had enrolled 22 patients with relapsed or refractory CD30+ Hodgkin and non-Hodgkin lymphoma having received a median of seven prior lines of therapy, of whom 19 were evaluable for response. Thirteen response-evaluable patients were treated at the RP2D, including 12 patients with Hodgkin Lymphoma and one patient with non-Hodgkin Lymphoma. Each treatment cycle consists of lymphodepleting chemotherapy with fludarabine and cyclophosphamide 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.

All 13 patients treated at the recommended phase 2 dose (10^8 NK/Kg) achieved a response by Lyric criteria. Of these 13 patients, 8 patients (62%) demonstrated a CR after two cycles of treatment, which represents an increase from 5 patients (38%) demonstrating CR after one cycle of treatment [previously announced in December 2021](#).

For the 13 patients treated at the RP2D, median duration of response has not yet been reached. As of the cutoff date, assessment of durability shows:

- Seven patients remain in CR at median follow-up of 6.5 months, including two patients who remain in response after 10 months and two patients who received stem cell transplant and remain in response at 6.5 months
- One patient with a CR experienced disease progression after 7.9 months
- Of the five patients with a PR, one remains in response at 6.3 months and four patients progressed between 2.9 and 4.3 months after initial infusion

The treatment was well tolerated, with minimal side effects beyond the expected myelosuppression from the preceding lymphodepleting chemotherapy. No instances of cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, or graft versus host disease were observed. There were six infusion-related reactions in 110 infusions (5.4%) of AFM13 alone and no reactions to the cord blood-derived NK cells precomplexed with AFM13.

“A year ago, we were struck with hopeful optimism when the first four patients in the study all showed a response. Now, we are again presenting data at AACR and the results not only hold strong in a larger patient population but also show an increasing number of CRs with early but encouraging durability,” commented Dr. Adi Hoess, Chief Executive Officer at Affimed. “These

ongoing successes with AFM13 represent an important milestone for Affimed and could mark a turning point in the innate immuno-oncology space, potentially setting the stage for expanding this approach to additional cancer indications. Our goal is to leverage the distinct features of our ROCK[®] platform to generate best-in-class ICE[®] molecules that drive effective innate immune cell activation for the benefit of broad patient populations, addressing hematologic and solid tumor malignancies.”

The trial was originally designed to include up to two cycles. To assess durability beyond two cycles, an amendment has been approved by the U.S. Food and Drug Administration to increase the length of treatment from two up to four cycles, enabling longer follow up of patients.

AFM13, a bispecific tetravalent ICE[®] molecule, is designed for high affinity binding, both to CD16A on NK cells and macrophages, and to CD30 on lymphoma cells. AFM13 is also being [investigated as a monotherapy](#) and can bind the patient’s own NK cells, thus boosting their existing capacity to fight cancerous cells. When precomplexed with AFM13, NK cells exhibit immediate expansion in the patient’s circulation which persists for at least two weeks.

Oral presentation details

Title: Innate cell engager (ICE[®]) AFM13 combined with preactivated and expanded cord blood (CB)-derived NK cells for patients with refractory/relapsed CD30+ lymphoma

Presentation: CT003

Session: Clinical Trials of Cellular Immunotherapies, Sunday, April 10, 1:00 – 3:00 p.m. CST

About the 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 pre-complexed 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 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 ([NCT04074746](https://clinicaltrials.gov/ct2/show/study/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). Additional details can be found at [www.clinicaltrials.gov \(NCT04101331\)](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, 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.

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, AFM24, AFM28 and our other product candidates, 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 SEC. 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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