



PRESS RELEASE

Affimed Provides Data Update from Two Phase 1/2a Trials with its Innate Cell Engager AFM24 in Solid Tumor Patients at the 37th SITC Annual Meeting

- Comprehensive correlative science findings from patients treated with AFM24 monotherapy indicate an activation of NK cells and their migration to the tumor
- Initial signs of clinical activity and a well-managed safety profile with no dose-limiting toxicities were shown in preliminary data from the combination study investigating AFM24 administered in combination with the immune checkpoint inhibitor atezolizumab
- Further data updates to be presented in poster sessions on November 10 and 11, 2022 and to be made available on Affimed's website

Heidelberg, Germany, November 7, 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 announced data updates from two phase 1/2a trials with AFM24, the company's tetravalent, bispecific innate cell engager (ICE®), in patients with solid tumors. AFM24 binds both EGFR on tumor cells and CD16A on natural killer (NK) cells and macrophages, thereby facilitating the killing of EGFR-positive tumor cells. Abstracts for the upcoming data presentations at the 37th Annual Meeting of the Society for Immunotherapy of Cancer (SITC) were published today. The full updated clinical data sets will be presented in two poster presentations on November 10 and November 11, 2022 and will be made available through the following link on Affimed's website: [Publications and Posters - Affimed](#)

“The new data presented at this conference demonstrate that AFM24 is capable to activate the innate but also the adaptive immune response in cancer patients while showing a very good safety profile. We are also very encouraged by the early efficacy data that we observe with the combination of AFM24 and atezolizumab,” said Andreas Harstrick, M.D., Affimed's Chief Medical Officer. “We look forward to the ongoing investigation of AFM24 in both trials as a new treatment option for a patient population that is in desperate need of effective therapies.”

Poster Number 729: Targeting Epidermal Growth Factor Receptor (EGFR)-Expressing Solid Tumors With AFM24, A Novel CD16A Bispecific Innate Cell Engager: Comprehensive Correlative Science Findings From A Phase 1 Study

The first poster presentation includes correlative science findings from the phase 1 part of the ongoing monotherapy phase 1/2a study ([NCT04259450](#)) evaluating the safety and efficacy of AFM24 in patients with metastatic, treatment-refractory EGFR-positive solid tumors. In total, 35 patients with a range of tumor types were treated to date including patients with colorectal cancer (19/35), non-small cell lung cancer (8/35) and other solid tumors (8/35) were treated.

NK cells in peripheral blood showed upregulation of activation markers which coincided with transient loss of NK cells from peripheral blood. This indicates migration of NK cells to the tumor. In addition, cytotoxic CD8-positive T-cell levels increased in the tumor, pointing to a crosstalk with the adaptive immune system.

In all patients, AFM24 monotherapy demonstrated a well-managed safety profile.

Poster Number 745: AFM24 and atezolizumab combination in patients with advanced epidermal growth factor receptor-expressing (EGFR-positive) solid tumors: Initial results from the Phase 1 dose-escalation study

The second poster to be presented at SITC will include a data update from the phase 1/2a combination study ([NCT05109442](https://clinicaltrials.gov/ct2/show/study/NCT05109442)) evaluating AFM24 together with Roche's PD-L1 checkpoint inhibitor atezolizumab (Tecentriq®) in patients with advanced, treatment-refractory EGFR+ solid tumors. The aim of the two-part study is to establish the recommended phase 2 dose (RP2D) of AFM24 in combination with atezolizumab as well as to assess initial data on the efficacy and safety of AFM24 in combination with atezolizumab.

So far, four patients with gastric (1/4) or pancreatic (3/4) adenocarcinomas have been enrolled in the first dose cohort, with three completing the safety lead-in phase and receiving 160 mg AFM24 and atezolizumab. The preliminary data indicate that the combination of AFM24 and atezolizumab is a promising approach, with no dose-limiting toxicities observed.

Among three patients evaluated in cohort 1, clinical activity was observed in two patients, while one patient awaited tumor assessment at cut-off date. One ongoing partial response was observed in a patient with gastric cancer and skin metastases who had rapidly progressed following four prior lines of therapy, including a PD-1 inhibitor, and an ongoing stable disease at 4+ months with symptomatic improvement was observed in a patient with pancreatic adenocarcinoma. Dose escalation is proceeding with an AFM24 dose of 480 mg.

Combining AFM24 with atezolizumab may synergistically enhance the innate and adaptive immune responses, respectively, to target EGFR-positive tumors.

For more information as well as to access the full abstracts, please visit <https://www.sitcancer.org/2022/abstracts/abstracts2022>.

Both posters will be made available on Affimed's website as of November 10, 2022, in line with SITC's embargo policy.

About AFM24

AFM24 is a tetravalent, bispecific innate cell engager (ICE®) that activates the innate immune system by binding to CD16A on innate immune cells and EGFR, a protein widely expressed on solid tumors, to kill cancer cells. Generated by Affimed's fit-for-purpose ROCK® platform, AFM24 represents a distinctive mechanism of action that uses EGFR as a docking site to engage innate immune cells for tumor cell killing through antibody-dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis.

Affimed is evaluating AFM24 as monotherapy and in combination with other cancer treatments in patients with advanced EGFR-expressing solid malignancies whose disease has progressed after treatment with previous anticancer therapies.

AFM24-101, a monotherapy, first-in-human phase 1/2a open-label, is a non-randomized, multi-center, multiple ascending dose escalation and expansion study. Additional details may be found at www.clinicaltrials.gov using the identifier NCT04259450.

AFM24 is also being evaluated in a phase 1/2a study in combination with Roche's PD-L1 checkpoint inhibitor atezolizumab (AFM24-102, NCT05109442).

Furthermore, Affimed and NKGen Biotech initiated a phase 1/2a study (AFM24-103), investigating AFM24 in combination with NKGen Biotech's NK cell SNK01 (NCT05099549).

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® 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.

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