
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 6-K

**Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934**

**For the month of December, 2021
Commission File Number: 001-36619**

Affimed N.V.

**Im Neuenheimer Feld 582,
69120 Heidelberg,
Germany
(Address of principal executive offices)**

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

AFFIMED N.V.

On December 9, 2021, Affimed N.V. (Nasdaq: AFMD) (“Affimed”) issued a press release titled “Affimed to Host Virtual Investor Call Today to Discuss Treatment of CD30-positive Lymphoma Patients with Cord Blood-derived Natural Killer Cells Pre-complexed with Innate Cell Engager AFM13.”

Affimed announced today that it will host today a financial community call to discuss recent findings from the investigator-sponsored trial (IST) at The University of Texas MD Anderson Cancer Center investigating the treatment of CD30-positive lymphoma patients with its innate cell engager (ICE®) AFM13, pre-complexed with cord blood-derived natural killer (cbNK) cells (AFM13-104).

A treatment cycle consists of lymphodepleting chemotherapy with fludarabine and cyclophosphamide followed two days later by a single infusion of cytokine-preactivated and expanded cbNK cells that are pre-complexed with AFM13, followed by three weekly infusions of AFM13 (200 mg) monotherapy. Responses are assessed on day 28 by FDG-PET and patients can receive up to two cycles. Three patients were treated with 1×10^6 , three patients with 1×10^7 and 13 patients with 1×10^8 AFM13-pre-complexed cbNK cells per kg body weight.

Response Assessment

A total of 19 patients with CD30-positive relapsed or refractory Hodgkin and non-Hodgkin lymphomas (17 and 2 patients, respectively) have been treated to date across three dose cohorts. According to investigator assessment, 17 of 19 patients had achieved an objective response (ORR 89.5%) to the treatment, with seven complete responses (CR 36.8%) and ten partial responses (PR 52.6%).

In patients treated at the RP2D level of 1×10^8 cbNK cells per kg, 12 of 13 had classical Hodgkin lymphoma and 1 patient had CD30-positive NHL. In this cohort, 100% of patients responded after the first cycle of treatment with five CRs (38.5%) and seven PRs (61.5%). All patients treated at the RP2D have now received a second cycle of therapy. Response evaluation after cycle 2 will be reported at a future scientific conference.

Initial Durability of Response Observations

Nine patients treated in the dose escalation phase of the study had follow-up at 6 months. Of note, the three patients treated at the RP2D remain in remission at 6 months after start of treatment, two without additional treatment and one on anti-PD-1 antibody maintenance.

In the four responders out of six treated at the two lower dose levels, one patient, who started treatment in September 2020, remains in remission after consolidation autologous stem cell transplant, and three relapsed at 3.4, 4.8 and 6.3 months after start of therapy.

Safety

Five reported cases of transient infusion related reactions were reported after the monotherapy infusions of AFM13. Of note, there were no instances of serious adverse events such as cytokine release syndrome, immune cell-associated neurotoxicity syndrome or graft-versus-host disease.

Conference Call/Webcast Information

The event today will include a review of Affimed’s approach to activating the innate immune system in the fight against cancer, preclinical data supporting the combination of Affimed’s ICE® molecules with adoptive NK cell transfer, a review of the treatment challenges and clinical opportunities for CD30+ lymphomas, and review of the interim data from AFM13-104 by the study’s principal investigator, Yago L. Nieto, M.D., Ph.D., professor of Stem Cell Transplantation and Cellular Therapy at of The University of Texas MD Anderson Cancer Center.

Affimed will host a conference call and webcast today, December 9th, 2021, at 8:30 a.m. EST. To access the call, please dial +1 (409) 220-9054 for U.S. callers, or +44 (0) 8000 323836 for international callers, and reference passcode 3065475 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/webcasts/investor-day/> or <https://edge.media-server.com/mmc/p/zzwismtq>. A replay of the webcast will be accessible at the same link for 30 days following the call.

A copy of the press release is attached hereto as Exhibit 99.1 and is being furnished and shall not be deemed filed or incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such a filing.

Forward-Looking Statements

This Current Report on Form 6-K 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, 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in Heidelberg, Germany on December 9, 2021.

AFFIMED N.V.

By: /s/ Adi Hoess

Name: Adi Hoess

Title: Chief Executive Officer

By: /s/ Angus Smith

Name: Angus Smith

Title: Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	Affirmed N.V. Press Release dated December 9, 2021



PRESS RELEASE

Affimed to Host Virtual Investor Call Today to Discuss Treatment of CD30-positive Lymphoma Patients with Cord Blood-derived Natural Killer Cells Pre-complexed with Innate Cell Engager AFM13

- For the 13 patients treated at the recommended phase 2 dose (RP2D) the response rate after one cycle of treatment remains at 100% with a 38.5% complete response (CR) rate; one additional patient completed cycle 1 at the RP2D and was assessed with a partial response (PR)
- Three of 3 patients treated with two cycles in the dose escalation part of the study at the RP2D remain in CR at 6 months after start of treatment
- Side effect profile shows only five instances of transient infusion-related reactions (IRR) in more than 100 AFM13 infusions with no episodes of neurotoxicity, CRS or GvHD

Heidelberg, Germany, December 9, 2021 – Affimed N.V. (Nasdaq: AFMD), a clinical-stage immuno-oncology company committed to giving patients back their innate ability to fight cancer will host today a financial community call to discuss recent findings from the investigator sponsored trial (IST) at The University of Texas MD Anderson Cancer Center investigating the treatment of CD30-positive lymphoma patients with its innate cell engager (ICE®) AFM13, pre-complexed with cord blood-derived natural killer (cbNK) cells (AFM13-104).

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About the Phase 1-2 Study

The University of Texas MD Anderson Cancer Center is studying AFM13 in an investigator-initiated phase 1-2 trial in combination with cord blood-derived allogeneic NK cells in patients with recurrent or refractory CD30-positive lymphomas. The first phase of this study involves dose escalation of pre-complexed NK cells, with patients receiving lymphodepleting chemotherapy followed by 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 to determine the recommended phase 2 dose and evaluate its activity. The recommended phase 2 dose was determined as 1×10^8 NK cells/kg. In each cohort, the dose of the pre-complexed NK cells with AFM13 is 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 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. Additional details can be found at www.clinicaltrials.gov (NCT04101331).

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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