## 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 November, 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):

#### **INCORPORATION BY REFERENCE**

On November 22, 2021, Affimed N.V. (Nasdaq: AFMD), a clinical-stage immuno-oncology company committed to giving patients back their innate ability to fight cancer, announced interim clinical results from the investigator-initiated phase 1-2 study at The University of Texas MD Anderson Cancer Center, evaluating cbNK cells pre-complexed with Affimed's innate cell engager (ICE®) AFM13.

The text above shall be be deemed to be incorporated by reference into the registration statements on Form F-3 (Registration Number 333-227933), Form F-3 (Registration Number 333-251648), Form F-3 (Registration Number 333-260946) and Form S-8 (Registration Numbers 333-198812) of Affimed N.V. and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished. Exhibit 99.1 to this Report on Form 6-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act.

#### 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 November 22, 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 Description of Exhibit

99.1 <u>Affimed N.V. Press Release dated November 22, 2021</u>



#### PRESS RELEASE

#### Affimed Announces 100% Objective Response Rate at Highest Dose in Phase 1-2 Study of Cord Blood-derived Natural Killer Cells Pre-complexed with Innate Cell Engager AFM13 for CD30-positive Lymphomas

- 100% objective response rate with a 42% complete response rate in 12 patients, according to investigator assessment, after the 1<sup>st</sup> of 2 planned cycles at the recommended phase 2 dose of 10<sup>8</sup> cord blood-derived natural killer (cbNK) cells/kg pre-complexed with AFM13
- No cases of serious adverse events such as cytokine release syndrome, neurotoxicity syndrome or graft-versus-host disease were observed
- Affimed to host virtual investor event on December 9<sup>th</sup> to discuss the results

**Heidelberg, Germany, November 22, 2021** – Affimed N.V. (Nasdaq: AFMD), a clinical-stage immuno-oncology company committed to giving patients back their innate ability to fight cancer, today announced interim clinical results from the investigator-initiated phase 1-2 study at The University of Texas MD Anderson Cancer Center, evaluating cbNK cells pre-complexed with Affimed's innate cell engager (ICE®) AFM13.

As of October 31, 2021, a total of 18 patients with CD30-positive relapsed or refractory Hodgkin and non-Hodgkin lymphomas (16 and 2 patients, respectively) were treated with the novel combination of cbNK cells pre-complexed with AFM13. 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 1x10<sup>6</sup>, three patients with 1x10<sup>7</sup> and 12 patients with 1x10<sup>8</sup> AFM13-pre-complexed cbNK cells per kg body weight.

As of the cutoff date, 16 of 18 patients had achieved an objective response to the treatment according to investigator assessment, with seven complete responses (CR) and nine partial responses (PR). Eleven of twelve patients treated at the recommended phase 2 dose level of 10<sup>8</sup> cbNK cells per kg had Hodgkin Lymphoma. In this cohort of patients treated at the recommended phase 2 dose, 100% responded after the first cycle of treatment with five CRs and seven PRs according to investigator assessment. Each of the patients in this cohort is eligible for a second treatment cycle, and updated data from this cohort will be reported at a later date. Treatment was well tolerated with five reported cases of transient infusion related reactions 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.

"The patients enrolled in this study were all heavily pre-treated with a median of 6 lines of prior therapy and had progressive disease after their previous line of therapy," said Dr. Andreas Harstrick, Chief Medical Officer at Affimed. "We are encouraged by the response rates that we continue to observe in these difficult to treat patients. The data are in line with data presented at AACR earlier this year. We also continue to see a very good safety profile of the combination, which is important as many of these patients have been very heavily pretreated and cannot tolerate aggressive therapies. Combining our ICE® molecules with NK cells is an integral part of our strategy to bring innovative therapies to patients in need. We believe these preliminary data provide further validation of this approach."

#### **Conference Call/Webcast Information**

Affimed will host a conference call and webcast on December 9th, 2021, at 8:30 a.m. EST to review the data. Affimed's management will discuss the results to date, the current treatment landscape for CD30+ lymphomas, and next steps for the study. Dr. Yago L. Nieto, M.D., Ph.D, Department of Stem Cell Transplantation and Cellular Therapy, Division of Cancer Medicine from M.D Anderson Cancer Center will also be available during the call.

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/investors/webcasts\_cp/ 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.

#### 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 bloodderived 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<sup>6</sup> NK cells/kg in Cohort 1; 1×10<sup>7</sup> NK cells/kg in Cohort 2; and 1×10<sup>8</sup> 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 1x10<sup>8</sup> 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<sup>®</sup>) 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<sup>®</sup> 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: <u>www.affimed.com</u>.

#### **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, 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.

#### **Investor Relations Contact**

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