
**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 March, 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 March 10, 2021, Affimed N.V. (Nasdaq: AFMD), a clinical-stage immuno-oncology company committed to giving patients back their innate ability to fight cancer, announced its decision to continue enrollment in the REDIRECT trial, which is evaluating AFM13 as a monotherapy for the treatment of patients with relapsed or refractory CD30-positive peripheral T-cell lymphoma (PTCL).

The decision to continue the trial followed a preplanned interim futility analysis. The interim analysis was triggered following enrollment of 20 patients in both Cohort A ($\geq 10\%$ CD30) and Cohort B ($>1\%$ to $<10\%$ CD30). The futility boundary was derived from response rates for previous therapies that have received accelerated approval in relapsed or refractory (R/R) PTCL. The futility analysis demonstrated that the response rate in Cohort A achieved the predefined threshold for continuation of the study. The response rate in Cohort B was sufficiently comparable to allow merging of both cohorts into a single cohort for all patients with CD30 $>1\%$, per the study protocol. Evidence of anti-tumor response was observed in both cohorts with complete and partial responses. The safety analysis was consistent with previously reported data from Affimed's Phase 1 trials of AFM13, with infusion related reactions (IRRs) representing the main side effect. Following the introduction of mandatory premedication, IRRs were markedly reduced, resulting in fewer dose reductions and a trend towards better activity.

The text above shall be deemed to be incorporated by reference into the registration statements on Form F-3 (Registration Number 333-227933) 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 March 10, 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 March 10, 2021



PRESS RELEASE

Affimed Announces Continuation of REDIRECT, a Registration-directed Study of AFM13 in PTCL, after Positive Preplanned Interim Futility Analysis

- Study will continue and combine cohorts of CD30 high and CD30 low expressing PTCL based on assessment from Independent Review Committee
- Objective responses observed in heavily pretreated patients in both cohorts
- Side effect profile similar to previously reported data
- Conference call scheduled for March 10th at 8:30 a.m. EST

Heidelberg, Germany, March 10, 2021 – Affimed N.V. (Nasdaq: AFMD), a clinical-stage immuno-oncology company committed to giving patients back their innate ability to fight cancer, announced today its decision to continue enrollment in the REDIRECT trial, which is evaluating AFM13 as a monotherapy for the treatment of patients with relapsed or refractory CD30-positive peripheral T-cell lymphoma (PTCL).

The decision to continue the trial followed a preplanned interim futility analysis. The interim analysis was triggered following enrollment of 20 patients in both Cohort A ($\geq 10\%$ CD30) and Cohort B ($>1\%$ to $<10\%$ CD30). The futility boundary was derived from response rates for previous therapies that have received accelerated approval in relapsed or refractory (R/R) PTCL. The futility analysis demonstrated that the response rate in Cohort A achieved the predefined threshold for continuation of the study. The response rate in Cohort B was sufficiently comparable to allow merging of both cohorts into a single cohort for all patients with CD30 $>1\%$, per the study protocol. Evidence of anti-tumor response was observed in both cohorts with complete and partial responses. The safety analysis was consistent with previously reported data from Affimed's Phase 1 trials of AFM13, with infusion related reactions (IRRs) representing the main side effect. Following the introduction of mandatory premedication, IRRs were markedly reduced, resulting in fewer dose reductions and a trend towards better activity.

“We are very encouraged by the observed activity of AFM13 in this heavily pretreated patient population, where more than half of the patients had three or more lines of previous therapy. These data reinforce our strategy to broadly develop AFM13 across CD30-positive lymphomas both as monotherapy and in combination with other therapies,” said Dr. Andreas Harstrick, Affimed's Chief Medical Officer. “Having successfully met the criteria for continuation, the trial will move forward by merging the CD30 high- and low-expressing PTCL cohorts for evaluation of the safety and efficacy of AFM13.”

“We are excited by this progress and by AFM13's potential as monotherapy for patients with PTCL,” said Dr. Won Seog Kim, Principal Investigator of REDIRECT and Professor of Hematology and Oncology at the Samsung Medical Center, Sungkyunkwan University, Seoul, Korea. “PTCL is an aggressive and challenging cancer to treat in patients who relapse or do not respond favorably to current therapies, which often have high toxicity profiles, and new therapeutic approaches are needed.”



AFM13 is also being evaluated in combination with cord-blood derived natural killer cells in CD30-positive lymphomas at MD Anderson Cancer Center (MDACC). Initial data from this investigator sponsored study will be presented at the American Association for Cancer Research (AACR) Annual Meeting in April 2021.

Investor Conference Call and Webcast Details Affimed will host an investor conference call and webcast today, Wednesday, March 10, at 8:30 a.m. EST, to review the REDIRECT study interim analysis. To access the call, please dial +1-646-741-3167 for U.S. callers, or +44 (0) 2071 928338 for international callers, and reference conference ID 6065008 approximately 15 minutes prior to the call. To access the live audio webcast of the conference call please visit the “Investors” section of the company’s website at https://www.affimed.com/investors/webcasts_cp/. A replay of the call will be archived on Affimed’s website for 30 days after the call.

About AFM13-202 and the REDIRECT Trial Design

REDIRECT (also known as AFM13-202, NCT04101331) is a registration-directed phase 2 open-label, multicenter, global study investigating the efficacy and safety of AFM13 monotherapy in patients with R/R CD30-positive PTCL and Transformed Mycosis Fungoides (TMF).

The study enrolls patients who suffer from CD30 expressing PTCL or TMF and who have relapsed after an earlier standard of care treatment or have refractory disease. Dependent on their disease type and the magnitude of CD30 expression on their tumor cells, study participants are assigned to one of three study cohorts, each cohort receiving the same treatment of weekly AFM13 infusions (a 200mg dose per infusion). The three cohorts are comprised of Cohort A, which includes PTCL patients with $\geq 10\%$ CD30 expression on tumor cells; Cohort B, which includes PTCL patients with $>1\%$ to $< 10\%$ CD30 expression on tumor cells; and, Cohort C, currently on hold, which includes TMF patients with $\geq 1\%$ CD30 expression on tumor cells.

The main goal of the study is to assess the efficacy of AFM13 treatment as judged by the rate of objective responses. Further goals of the study are to assess the safety of AFM13 treatment, the immunogenicity of AFM13 (as measured by the formation of anti-AFM13 antibodies) and the concentration of AFM13 in the blood.

The study began recruitment in October 2019 at sites in the United States, Australia, South Korea and seven European countries. The TMF arm of the study (Cohort C), which is exploratory only and not relevant to the potential consideration for accelerated approval, will remain paused, due to COVID-19 and the high number of assessments and site visits necessary for this group of patients. To date, no TMF patients have been recruited into the study.



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.

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, 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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