## 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 October, 2018

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**

Exhibit 99 to this Report on Form 6-K shall be deemed to be incorporated by reference into the registration statements on Form F-3 (Registration Number 333-207235) 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333-198812) of Affimed N.V. and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

## 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, October 8, 2018.

## AFFIMED N.V.

<u>By:</u> /s/ Adi Hoess

Name: Adi Hoess Title: Chief Executive Officer

<u>By:</u> /s/ Florian Fischer

Name: Florian Fischer Title: Chief Financial Officer ExhibitDescription of Exhibit99Press Release dated October 8, 2018



## FOR IMMEDIATE RELEASE

## Affimed Places AFM11 (CD19/CD3-Targeting T cell Engager) Phase 1 Program on Clinical Hold

*Heidelberg, Germany, October 8, 2018* - Affimed N.V. (Nasdaq: AFMD), a clinical stage biopharmaceutical company focused on discovering and developing highly targeted cancer immunotherapies that harness the power of innate and adaptive immunity (NK and T cells), today announced that it has placed AFM11 (CD19/CD3-targeting T cell engager) on clinical hold, and has notified the global health authorities of its decision. AFM11 is being evaluated in two Phase 1 clinical studies for the treatment of patients with relapsed or refractory CD19 positive B-cell non-Hodgkin lymphoma (NHL) and acute lymphoblastic leukemia (ALL). The clinical hold was initiated after the occurrence of Serious Adverse Events (SAEs) in three patients, which included a death in the ALL study and two life-threatening events in the NHL study.

The SAEs occurred in patients enrolled in the highest dose cohorts of each study. Thirty-three patients have been treated in total in the two Phase 1 studies, with preliminary signs of clinical activity observed in several patients.

Affimed will be working closely with the global health authorities, the Safety Monitoring Committees, and the studies' clinical investigators to review the events, carefully assess all of the data and determine next steps for the AFM11 program. Affimed intends to provide an update on AFM11 upon completion of the evaluation.

The clinical hold does not affect the ongoing development of Affimed's NK cell engager programs, which are based on targeting the NK cell receptor CD16A, a different approach than used for AFM11, which targets T cells through CD3.

1

## About Affimed N.V.

Affimed (Nasdaq: AFMD) engineers targeted immunotherapies, seeking to cure patients by harnessing the power of innate and adaptive immunity (NK and T cells). We are developing single and combination therapies to treat cancers and other life-threatening diseases. For more information, 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 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, expectations regarding 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 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.

#### Affimed Investor Contact:

Gregory Gin, Head of Investor Relations E-Mail: IR@affimed.com

#### **Affimed Media Contact:**

Anca Alexandru, Head of Communications, EU IR E-Mail: media@affimed.com