



**FOR IMMEDIATE RELEASE**

## **Affimed Announces FDA Clearance of IND to Commence First-in-Human Phase 1/2a Study of AFM24 for the Treatment of EGFR-Expressing Cancers**

- *Activation of innate immunity to target EGFR-expressing solid tumors has potential to address limitations associated with currently available EGFR-targeted therapies*
- *Initiation of Phase 1/2a clinical trial expected in first half of 2020*

*Heidelberg, Germany, November 7, 2019* - Affimed N.V. (Nasdaq: AFMD), a clinical stage biopharmaceutical company committed to giving patients back their innate ability to fight cancer, today announced that its Investigational New Drug application (IND) has cleared the required 30-day review by the U.S. Food and Drug Administration (FDA) and is in effect for a Phase 1/2a clinical trial of AFM24, a tetravalent, bispecific epidermal growth factor receptor (EGFR)- and CD16A-binding innate cell engager, in patients with advanced cancers known to express EGFR.

“The IND clearance of AFM24 enables us to proceed with our planned Phase 1/2a study aimed at establishing safety and identifying initial signals of efficacy in patients with EGFR-expressing solid tumors,” said Dr. Adi Hoess, Chief Executive Officer of Affimed. “There is a tremendous need for novel immuno-oncology approaches and based on its novel mechanism of activating the innate immune system, AFM24 has the potential to address limitations, such as toxicities or resistance, associated with other EGFR-targeted therapies.”

The initial goal of the planned Phase 1/2a study is to determine the maximum tolerated dose and recommended Phase 2 dose of AFM24, as well as to evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy. The second part of the study is designed to evaluate the preliminary efficacy of AFM24 in patients with select solid tumor subtypes. The study is planned to initiate in the first half of 2020.

AFM24 has the potential to provide a meaningful benefit to a broad set of patients suffering from EGFR-expressing tumors, including those patients who currently are not being addressed by existing EGFR-targeted therapies. According to internal market research, leading clinical experts

across multiple cancer indications see a tremendous need for novel immuno-oncology approaches for the treatment of solid tumors. Preclinical data showed AFM24's ability to bridge NK cells and macrophages to EGFR-expressing tumor cell lines and induce cell lysis through antibody-dependent cellular cytotoxicity (ADCC), independent of RAS mutational status, and antibody-dependent cellular phagocytosis (ADCP). In addition, AFM24 enhanced tumor infiltration of NK cells and elicited dose-dependent anti-tumor efficacy in in vivo tumor models. Treatment of cynomolgus monkeys with AFM24 showed a favorable safety profile, even when the animals were treated at high dose levels, demonstrating AFM24's potential to have lower toxicities in humans compared to other EGFR-targeted therapeutics.

### **About AFM24**

AFM24, a tetravalent, bispecific EGFR- and CD16A-binding innate cell engager from Affimed's fit-for-purpose ROCK<sup>®</sup> platform, is designed to address limitations associated with other EGFR-targeted therapies, such as toxicities or resistance, by using a new mechanism of action to target EGFR-expressing solid tumors through activation of innate immunity rather than inhibition of EGFR-mediated signal transduction.

### **About Affimed N.V.**

Affimed (Nasdaq: AFMD) is a clinical stage biopharmaceutical company committed to giving patients back their innate ability to fight cancer. Affimed's fit-for-purpose ROCK<sup>®</sup> platform allows innate cell engagers to be designed for specific patient populations. The Company is developing single and combination therapies to treat hematologic and solid tumors. For more information, please visit [www.affimed.com](http://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 value of our ROCK<sup>®</sup> 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.

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