



## **Affimed Announces First Patient Successfully Dosed in First-in-Human Phase 1/2A Study of AFM24 for the Treatment of Advanced EGFR-Expressing Solid Tumors Including Colon, Lung and Other Cancers**

- *AFM24, designed to activate innate immunity to broadly target EGFR-expressing solid tumors regardless of mutational status, has the potential to improve efficacy and safety over currently available EGFR-targeted therapies*
- *AFM24 is the first innate cell redirecting immuno-oncology therapeutic dosed in solid tumor patients*

*Heidelberg, Germany, April 16, 2020* – Affimed N.V. (Nasdaq: AFMD), a clinical-stage immuno-oncology company committed to giving patients back their innate ability to fight cancer, today announced that the first patient was successfully dosed in a Phase 1/2a clinical trial of AFM24, a first in human study evaluating AFM24 as monotherapy in patients with advanced solid malignancies whose disease has progressed after treatment with previous anticancer therapies. AFM24, a tetravalent, bispecific epidermal growth factor receptor (EGFR)- and CD16A-binding innate cell engager, is novel due to its activation of innate immunity to kill solid tumors, inducing both antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP), as compared to other therapies that rely heavily on signal or checkpoint inhibition.

“Today is a landmark day for Affimed and, more importantly, for patients whose solid tumors continue to progress,” said Dr. Adi Hoess, Chief Executive Officer of Affimed. “This major milestone marks the first time a patient with solid tumors has been dosed with an innate cell engager. AFM24 has demonstrated preclinically the ability to bridge NK cells and macrophages to EGFR-expressing tumor cell lines, and to induce lysis through ADCC and ADCP, respectively, independent of RAS mutational status. We look forward to the continued study of this novel agent and further validating its safety and efficacy through this human clinical trial.”

“Initiation of dosing in the first in human clinical trial of AFM24 is exciting news for the broad set of patients with hard to treat EGFR-expressing cancers,” said Dr. Anthony El-Khoueiry, Phase I program director at the USC Norris Comprehensive Cancer Center and Keck School of Medicine, and principal investigator for the study. “While available EGFR therapies have improved the lives of patients, new

therapeutic options are needed that are broadly efficacious, easier for patients to tolerate and can also address the issue of resistance associated with currently available treatments.”

The study is an open-label, non-randomized, multi-center, multiple ascending dose escalation/expansion study to evaluate AFM24 as monotherapy in adult patients with advanced solid malignancies known to be EGFR-positive. The aim of the dose escalation phase is the determination of the maximum tolerated dose and the establishment of a recommended Phase 2a dose. The dose expansion phase is intended to collect preliminary evidence of efficacy and to further confirm the safety of AFM24. For more information including eligibility criteria, visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov), using Identifier NCT04259450.

### **About AFM24**

AFM24 is a tetravalent, bispecific EGFR- and CD16A-binding innate cell engager generated from Affimed’s fit-for-purpose ROCK® platform. AFM24 uses the cytotoxic potential of the innate immune system by redirecting and activating NK cells and macrophages to kill EGFR-positive cancer cells through antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP), respectively. Due to its unique mechanism of action, AFM24 is potentially not limited to patient subtypes based on mutational status. 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 therapies.

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

Affimed (Nasdaq: AFMD) is a clinical-stage immuno-oncology company committed to giving patients back their innate ability to fight cancer. Affimed’s fit-for-purpose ROCK® 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. The company’s initial clinical program, AFM13 for CD30-positive lymphomas, is currently enrolling patients for a registration-directed study in relapsed/refractory peripheral T cell lymphoma. 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 potential of AFM24, 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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