



## **Affimed Announces FDA Granted Orphan Drug Designation for Lead Innate Cell Engager AFM13 for the Treatment of T-cell Lymphoma**

*Heidelberg, Germany, April 1, 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 U.S. Food and Drug Administration (FDA) has granted orphan drug designation to AFM13, its lead CD30- and CD16A-binding innate cell engager, for the treatment of patients with T-cell lymphoma. The granted designation includes peripheral T cell lymphoma (pTCL), a subtype of T-cell lymphoma. AFM13 is being investigated as a monotherapy for the treatment of relapsed or refractory CD30-positive pTCL in a Phase 2 registration-directed study.

The FDA may grant orphan designation to drugs and biologics intended to treat a rare disease or condition affecting fewer than 200,000 persons in the U.S. The designation qualifies a company for certain benefits, including financial incentives to support clinical development and the potential for seven years of market exclusivity in the U.S. upon regulatory approval.

### **About AFM13**

AFM13 is a first-in-class tetravalent, bispecific innate cell engager that specifically binds to CD30 on tumor cells and to CD16A on NK cells. AFM13 is being developed in peripheral T cell lymphoma (pTCL) and in other CD30-positive lymphomas. AFM13 has shown a favorable safety profile and signs of therapeutic efficacy as a monotherapy in CD30-positive non-Hodgkin lymphoma with cutaneous manifestation. In addition, data from a combination study of AFM13 with Merck's anti-PD-1 antibody Keytruda® (pembrolizumab) in Hodgkin lymphoma (HL) supports proof of principle for the combination of NK cell engagement with checkpoint inhibition. AFM13 has been granted orphan drug designation by the U.S. Food and Drug Administration for HL.

### **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. 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® 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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