



FOR IMMEDIATE RELEASE

## **Affimed Reports New Data for AFM13 from Two Separate Clinical Trials in Hodgkin and CD30-Positive Lymphomas**

***Data Demonstrate AFM13 in Combination with Keytruda® (Pembrolizumab) Doubled Complete Response Rate in Hodgkin Lymphoma Patients***

***Early Data Suggest New Opportunity for AFM13 in CD30-positive Lymphoma***

***AFM13 is Clinically Active and Well-tolerated as Mono- and Combination Therapy***

Heidelberg, Germany, February 1, 2018 - Affimed N.V. (Nasdaq: AFMD), a clinical stage biopharmaceutical company focused on discovering and developing highly targeted cancer immunotherapies, today reported additional preliminary patient data from two separate clinical studies of its lead NK cell engager candidate AFM13. The data demonstrate that AFM13 was well-tolerated and showed promising therapeutic efficacy both in combination with the anti-PD-1 antibody Keytruda® (pembrolizumab) in Hodgkin lymphoma (HL) and as monotherapy in CD30-positive lymphoma.

“We are extremely encouraged by these new data which indicate that the first-in-class NK cell engager AFM13 has achieved clinically meaningful responses both as single agent and in combination with a checkpoint inhibitor” said Dr. Adi Hoess, CEO of Affimed. “In particular, in our combination trial with Keytruda, we are excited to have increased both overall and complete metabolic response rates.”

### **AFM13 in combination with Keytruda® in relapsed/refractory HL**

Best response preliminary assessment data from 9 patients treated at the highest AFM13 dose level (7 mg/kg) as reported by central read, showed an objective response rate (ORR) of 89% (8/9), including complete metabolic responses (CmR) in 44% (4/9) and partial metabolic responses

(PmRs) in 44% (4/9) of patients. One patient experienced stable disease (SD). This ORR of 89% compared favorably to the historical ORR of Keytruda (58-63%) as monotherapy in a similar patient population. Namely, these patients were R/R HL and post autologous stem cell transplantation (ASCT) or ineligible for ASCT and had failed brentuximab vedotin (BV). Importantly, the reported CR rate of 44% represents a doubled CR rate compared to previously reported anti-PD1 studies (9-22%).

The combination was well-tolerated with most of the adverse events observed mild to moderate in nature and manageable with standard of care.

The data shown here comprise six previously reported patients, including one patient evaluated as a PmR at the three-month assessment and who was converted into CmR at the six-month assessment, as well as three additional patients. In total, the extension cohort includes 21 patients and enrollment has recently been completed.

#### **AFM13 as monotherapy in relapsed/refractory CD30-positive cutaneous lymphoma**

In an ongoing investigator-sponsored Phase 1b/2a trial of AFM13 in CD30-positive lymphoma with cutaneous manifestation led by Columbia University Medical Center, an analysis of the first dose cohort (3 patients dosed at 1.5 mg/kg) has been completed. The data demonstrated that AFM13 could be safely administered and showed therapeutic activity as a single agent, with an ORR of 66% (2/3). In detail, one complete response (CR), one partial response (PR) and one stable disease (SD) were observed, as determined by global response score (GRS).

"AFM13 is a truly novel immuno-therapeutic that recruits NK cells and targets CD30-expressing lymphomas. Our early clinical experience has been impressive", said Dr. Ahmed Sawas, Assistant Professor of Medicine at the Columbia University College of Physicians and Surgeons and the New York-Presbyterian Hospital and Principal Investigator of the study. "The treatment was well-tolerated and, importantly, it could provide a new treatment for relapsed/refractory CD30-positive lymphoma patients, who currently have limited to no options."

The data shown here comprise one previously reported patient as well as two additional patients. In total, the trial includes three cohorts of three patients each and enrollment is currently ongoing into the third dose cohort.

These data further highlight the clinical utility of NK cell engagement in CD30-positive lymphoma, an indication with high unmet medical need, providing an opportunity for AFM13 beyond classical HL.

### **About AFM13**

AFM13 is a first-in-class tetravalent, bispecific NK cell engager that specifically binds to CD30 on tumor cells and to CD16A on NK cells. AFM13 is being developed in Hodgkin lymphoma (HL) and in other CD30-positive lymphomas. AFM13 has shown a favorable safety profile and signs of therapeutic efficacy in a monotherapy setting in studies in HL and CD30+ lymphoma with cutaneous manifestation. In addition, data from a combination study of AFM13 with Merck's anti-PD1 antibody Keytruda® (pembrolizumab) supports proof of principle for the combination of NK cell engagement with checkpoint inhibition.

### **About Affimed's Phase 1b study of AFM13 in combination with Keytruda (pembrolizumab) (NCT02665650)**

Ongoing Phase 1b study to evaluate the safety and tolerability of the combination of the Affimed's lead product candidate AFM13 with pembrolizumab (Keytruda®) as salvage therapy after failure of standard therapies including brentuximab vedotin (BV) in relapsed or refractory (R/R) Hodgkin lymphoma (HL). Patients received escalating doses of AFM13 in combination with pembrolizumab at a flat dose of 200 mg administered every 3 weeks following the classical 3+3 design. Recruitment has been completed into an extension cohort at the highest dose level explored during dose escalation. Response assessment is performed every 12 weeks by PET/CT according to the Lugano Classification Revised Staging System for malignant lymphoma.

### **About Columbia University's Phase 1b/2a study of AFM13 in CD30-positive lymphoma (NCT03192202)**

Ongoing investigator-sponsored translational Phase 1b/2a study of Affimed's lead product candidate AFM13 in patients with relapsed or refractory CD30-positive lymphoma with cutaneous manifestation led by the Columbia University Medical Center. Primary objective of this study is to investigate the biologic and immunologic effects induced by the administration of various doses of AFM13, when given as a single agent in a broad spectrum of CD30-positive lymphomas with cutaneous presentation. The study is designed to allow for serial biopsies, thereby enabling assessment of NK cell biology and tumor cell killing within the tumor microenvironment.

### **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 [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 safety and efficacy of our product candidates, 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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