



**FOR IMMEDIATE RELEASE**

## **Affimed Enters into Collaboration with Merck to Evaluate AFM13 in Combination with KEYTRUDA<sup>®</sup> (pembrolizumab) for Patients with Hodgkin Lymphoma**

*Heidelberg, Germany, January 25, 2016* - Affimed N.V. (Nasdaq: AFMD), a clinical stage biopharmaceutical company focused on discovering and developing highly targeted cancer immunotherapies, announced today that it has entered into a clinical research collaboration in immuno-oncology with Merck (NYSE: MRK), known as MSD outside the United States and Canada. Under the terms of the agreement, Affimed will fund and conduct a Phase 1b clinical trial to investigate the combination of Merck's anti-PD-1 therapy, KEYTRUDA<sup>®</sup> (pembrolizumab), with Affimed's proprietary drug candidate AFM13 for the treatment of patients with Hodgkin lymphoma whose disease has relapsed or is refractory to chemotherapy, including treatment with the marketed antibody-drug-conjugate Adcetris<sup>™</sup> (brentuximab vedotin). Merck will supply Affimed with KEYTRUDA for the clinical trial. The purpose of the study is to establish a dosing regimen for this combination therapy and assess its safety and efficacy. Affimed is on track to initiate the study in the first half of 2016.

AFM13 is a bispecific antibody targeting CD30, an antigen specifically expressed in a variety of T- and B-cell lymphomas and targeting CD16A, an antigen expressed on natural killer (NK-) cells, which are important for the activation of the innate immune system and the subsequent killing of tumor cells. KEYTRUDA is a humanized monoclonal antibody that works by increasing the ability of the body's immune system to help detect and fight tumor cells. KEYTRUDA blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes, which may affect both tumor cells and healthy cells.

In patient-derived xenograft models, AFM13, in combination with an anti-PD-1 antibody, demonstrated impressive synergy, with up to 90 percent of the tumor eradicated. In this preclinical work, conducted at Stanford University, it was also shown that both NK- and T-cells infiltrated the tumors and that cytokine levels, including notably interferon-gamma, were elevated.

"Our development strategy is to combine our NK-cell engagers with other immunotherapies that could enhance their efficacy through the uptake of both NK-cells and T-cells, and the collaboration with Merck is an important step in executing this strategy," said Dr. Adi Hoess, CEO of Affimed. "AFM13, a first-in-class NK-cell engager, has shown an acceptable safety profile and preliminary

antitumor activity in the first-in-human Phase 1 study. Additionally, preclinical studies indicate that a combination with an anti PD-1 therapy could act synergistically and represent an additional future treatment option for patients.”

“Evaluating the potential for innovative combination therapies through strategic collaborations in difficult-to-treat tumor types continues to be an important part of our clinical development program for KEYTRUDA,” said Dr. Eric Rubin, vice president and therapeutic area head, oncology early-stage development, Merck Research Laboratories. “In partnering with companies such as Affimed, we continue our efforts to bring forward new scientific breakthroughs for patients with Hodgkin lymphoma and the field of immuno-oncology overall.”

The agreement is between Affimed and Merck, through a subsidiary. The collaboration agreement includes a provision for the potential expansion of the collaboration to include a subsequent Phase 3 clinical trial. Additional details were not disclosed.

### **About AFM13**

AFM13 is a first-in-class bispecific NK-cell TandAb<sup>®</sup>, which binds NK-cells (natural killer cells) specifically via CD16A and has a second binding domain for CD30, a cancer-specific target. CD16A is expressed on NK-cells, highly potent cytotoxic effector cells of the innate immune system, enabling AFM13 to selectively bind these effector cells. AFM13 redirects the NK-cells to CD30 expressing cancer cells and binds both targets with high affinity, establishing a bridge, whereby the NK-cells are activated and redirected to kill the cancer cells. AFM13 is designed to treat CD30-positive malignancies including Hodgkin lymphoma (HL) and T-cell lymphoma (TCL) and it is currently in Phase 2 studies in HL patients. Like all TandAbs<sup>®</sup>, AFM13 is a stable, off-the-shelf, targeted immunotherapeutic which does not require continuous infusion due to a favorable half-life in a patient’s bloodstream, yet is tunable by dosing adjustment when required. This highly specific NK-cell antibody and the related bispecific platform are unique to Affimed.

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

Affimed (Nasdaq: AFMD) is a clinical-stage biopharmaceutical company focused on discovering and developing highly targeted cancer immunotherapies. Affimed’s product candidates are being developed in the field of immuno-oncology, which represents an innovative approach to cancer treatment that seeks to harness the body’s own immune defenses to fight tumor cells. The most potent cells of the human defense arsenal are types of white blood cells called natural killer cells, or NK-cells, and T-cells. Affimed’s proprietary, next-generation bispecific antibodies, called TandAbs for their tandem antibody structure, are designed to direct and establish a bridge between either NK-cells or T-cells and cancer cells, triggering a signal cascade that leads to the destruction of cancer cells. Affimed has focused its research and development efforts on three proprietary TandAb programs for which it retains global commercial rights. For more information, please visit [www.affimed.com](http://www.affimed.com).

## **Forward-Looking Statements of Affimed N.V.**

This press release contains forward-looking statements within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. 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 are based on management's beliefs and assumptions and on information available to management only as of the date of this press release. These forward-looking statements include, but are not limited to, statements regarding the risk of cessation or delay of any of our ongoing or planned clinical studies and/or development of our product candidates, as well as statements regarding our collaborations and development of our products in combination with other therapies. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, without limitation, risks associated with our clinical development activities, regulatory oversight, product commercialization, collaborations, intellectual property claims, 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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