



**FOR IMMEDIATE RELEASE**

## **Affimed Presents Data at ASH 2018 Substantiating Opportunity for AFM13 as Mono- and Combination Therapy in CD30-Positive Tumors**

- Data Confirm Clinical Single-Agent Activity of AFM13 in CD30-Positive Lymphoma with Cutaneous Presentation and Doubled Complete Response Rate of AFM13 in Combination with Keytruda® (Pembrolizumab) in Hodgkin Lymphoma Patients -*
- Future Combination Opportunities Include Combination of CD16A Immune Cell Engagers with Adoptive NK Cell Transfer -*

*Heidelberg, Germany, December 3, 2018* - Affimed N.V. (Nasdaq: AFMD), a clinical stage biopharmaceutical company focused on discovering and developing highly targeted cancer immunotherapies that harness the power of innate and adaptive immunity (NK cells, macrophages and T cells), today announced six presentations highlighting data from the Company's innate immune cell and T cell-based therapeutics programs at the 60<sup>th</sup> American Society of Hematology (ASH) Annual Meeting and Exposition, being held December 1-4, 2018 in San Diego, CA.

Three of the presentations featured data supporting the potential of AFM13, Affimed's lead CD30/CD16A bispecific ROCK<sup>®</sup> based innate immune cell engager as monotherapy or in combinations with a checkpoint inhibitor and cord blood-derived allogeneic NK cells, respectively.

"The data presented at ASH substantiate the opportunity we see to develop AFM13 as mono- and combination therapy," said Dr. Adi Hoess, CEO of Affimed. "AFM13 could provide a new treatment for relapsed/refractory CD30-positive lymphoma patients, while the combination of AFM13 with pembrolizumab showed highly encouraging response and durability data in patients with relapsed/refractory Hodgkin lymphoma. We look forward to providing an update on our clinical development strategy for AFM13 at our upcoming R&D Day on December 7."

### **AFM13 as monotherapy in relapsed/refractory CD30-positive cutaneous lymphoma (Abstract #2908)**

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 Phase 1b/2a trial of AFM13 in CD30-positive lymphoma with cutaneous manifestation (NCT03192202) highlighted data from the ongoing investigator-sponsored study. An analysis of the first three dose cohorts (9 patients dosed at 1.5-7.0 mg/kg) demonstrated that AFM13 could be safely administered and showed therapeutic activity as a single agent, with an objective response rate (ORR) of 44% (4/9). In detail, one complete response (CR), three partial responses (PRs) and two stable diseases (SDs) were observed, as determined by global response score (GRS). An analysis of biomarker correlatives showed a temporary decrease in circulating NK cells (CD56<sup>+</sup> CD3<sup>-</sup>, CD56<sup>+</sup> CD16<sup>+</sup>, NKp46<sup>+</sup>) during therapy, with post-therapy recovery. In addition, increased CD69 expression on circulating NK cells from responders vs. non-responders was demonstrated. Tumor biopsies showed increased infiltration of CD56<sup>+</sup> NK cells in responders compared to non-responders, while circulating CD4<sup>+</sup> CD25<sup>+</sup> T cells (Tregs) decreased in responders compared to non-responders.

"Our clinical experience with AFM13 continues to be impressive," commented Dr. Sawas. "AFM13 is well-tolerated and active in patients who have failed therapy with brentuximab vedotin and, importantly, it demonstrated a high ORR of 44% in CD30-positive lymphoma patients with very limited to no treatment options. Our biomarker data indicate a possible correlation between response and tumor NK cell infiltration pre-therapy. Overall, the data presented here support the potential of AFM13 as a novel immuno-therapeutic to treat CD30-expressing lymphomas."

### **AFM13 in combination with Keytruda® in relapsed/refractory HL (Abstract #1620)**

Affirmed provided an update on its Phase 1b trial of AFM13 in combination with Merck's Keytruda® (pembrolizumab) in Hodgkin lymphoma (HL; NCT02665650). The patient population of this study comprises relapsed or refractory HL patients post autologous stem cell transplantation (ASCT) or ineligible for ASCT, who had failed brentuximab vedotin. The combination was well-tolerated with most of the adverse events observed mild to moderate in nature and manageable with standard of care. Best response assessment data from 24 patients treated at the highest AFM13 dose level (7 mg/kg) as reported by central read, showed an ORR of 88% (21/24), including complete metabolic responses (CmR) in 46% (11/24) and partial metabolic responses (PmRs) in 42% (10/24) of patients. One patient experienced stable disease (SD). Deepening of responses over time was observed in multiple patients, and patients who were previously transplant ineligible transitioned to transplant after achieving an objective response. The ORR of 88% and CR rates of 42% and 46% by local and central reads, respectively, compare favorably to the historical data of pembrolizumab in a similar patient population, with the CR rate approximately double that of pembrolizumab.

### **AFM13 in combination with adoptive NK cell transfer (Abstract #341)**

In an oral presentation, Lucila Kerbauy, MD from the Department of Stem Cell Transplantation and Cellular Therapy, The University of Texas MD Anderson Cancer Center (MDACC), described the successful development of a novel premixed product comprising expanded cord blood-derived NK cells (CB-NK cells) loaded with AFM13 to redirect their specificity against CD30-positive malignancies as well as *in vivo* data confirming the antitumor activity of these AFM13-NK cells. The encouraging *in vitro* and *in vivo* data observed in this study under Affimed's sponsored research collaboration with MDACC, provide a strong rationale for clinically investigating the strategy of an off-the-shelf adoptive immunotherapy with AFM13-loaded CB-NK cells in patients with relapsed/refractory CD30-positive malignancies.

In addition, Affimed presented data from a study investigating the role of ROCK<sup>®</sup> based CD16A immuno-engagers in activating CD16A-expressing macrophages to eliminate tumor cells (Abstract #1111). The data demonstrated that different CD16A immuno-engagers binding a variety of tumor targets were able to induce antibody-dependent cellular phagocytosis (ADCP) in a tumor antigen-specific manner in different CD16-positive macrophage subtypes, showing for the first time that macrophages contribute to the ROCK<sup>®</sup> CD16A immuno-engager mechanism of action.

Further presentations were an overview of the Company's partnered development candidate AFM26 (BCMA/CD16A) for patients with multiple myeloma in the context of the ROCK<sup>®</sup> platform (Abstract #1927) as well as interim results from its dose escalation trial in relapsed/refractory acute lymphoblastic leukemia (ALL) for AFM11, Affimed's CD19 targeting T cell engager (Abstract #3969).

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

Affimed (Nasdaq: AFMD) engineers targeted immunotherapies, seeking to cure patients by harnessing the power of innate and adaptive immunity (NK cells, macrophages 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 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, 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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