



## **Affimed Announces Publication of Final Study Results of its Innate Cell Engager Candidate AFM13 in Combination with MSD's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in *Blood***

- *The phase 1b study showed a complete response (CR) rate of 46% (objective response rate [ORR] of 88%) at the recommended dose level in patients with relapsed/refractory (R/R) Hodgkin lymphoma, whereas in a separate study MSD's KEYTRUDA demonstrated an ORR of 69% and a CR of 22.4% as a monotherapy*
- *Investigators concluded that AFM13 in combination with KEYTRUDA for R/R Hodgkin lymphoma patients was well-tolerated with adverse events that were generally manageable*
- *Novel immunotherapy combination worthy of further investigation*

**Heidelberg, Germany, November 19, 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 Phase 1b study of AFM13, a CD30/CD16A innate cell engager (ICE®), in combination with KEYTRUDA was published in *Blood*, the renowned Journal of the American Society of Hematology. The results demonstrate promising signs of efficacy including an objective response rate (ORR) of 88% at the highest treatment dose, as well as a complete CR of 46%. As a monotherapy, KEYTRUDA demonstrated an ORR of 69% and a CR of 22.4% in the KEYNOTE-087 trial.

“We showed for the first time that the combination of an ICE® with a PD-1 checkpoint inhibitor can be safely administered with manageable side effects,” said Dr. Andreas Harstrick, Chief Medical Officer at Affimed. “The high objective response rate and complete response rate seen in this proof-of-concept study of AFM13 combined with KEYTRUDA are very encouraging and indicate that the activation of innate immunity could improve upon current therapies.”

The study assessed the safety and efficacy of AFM13 in combination with KEYTRUDA in 30 heavily pre-treated patients with R/R Hodgkin lymphoma. The safety profile for the combination was described as well-tolerated and similar to the known profiles for each agent alone. Most adverse events were low grade and remained manageable with standard-of-care therapies.

AFM13 presents a novel approach of activating innate immunity through CD16A-directed tumor-cell killing by NK cells and macrophages. The phase 1b study supports the notion that in combination with an established therapy such as an immune checkpoint inhibitor, that releases the brakes on adaptive immune responses, the ICE® AFM13 complements the PD-1 checkpoint inhibitor, thereby triggering both arms of the immune system against tumors.

Dr. Nancy Bartlett, a medical oncologist and Koman Chair in Medical Oncology at Washington University School of Medicine in St. Louis and lead author on the publication, said, “There is an unmet need for patients with Hodgkin lymphoma who have relapsed or are refractory to current therapies. For these patients, there are no therapies that show durable efficacy. The combination of AFM13 with KEYTRUDA was well tolerated and showed an 88% response rate with a very encouraging 46% complete metabolic response rate in a heavily pretreated patient population. This exciting data shows that there are potential treatments on the horizon for patients with limited options.”

“Engagement of the innate immune system to kill tumors is novel. The studies of AFM13 and KEYTRUDA in Hodgkin lymphoma, as well as AFM13 in patients with T-cell lymphoma, present exciting approaches to controlling blood cancers that could significantly benefit patients,” said Lee Greenberger, Ph.D., Chief Scientific Officer of The Leukemia & Lymphoma Society (LLS), which supported Affimed’s clinical study of AFM13 through its [Therapy Acceleration Program® \(TAP\)](#), LLS’s strategic venture philanthropy funding initiative.

More details about the Phase 1b of AFM13 in combination with KEYTRUDA study can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) using the identifier NCT02665650. The article published in Blood, Volume 136, Number 21 can be found here <https://bit.ly/2KiL293>.

### **About AFM13**

AFM13 is a first-in-class innate cell engager that induces specific and selective killing of CD30-positive tumor cells by engaging and activating natural killer (NK) cells and macrophages, thereby leveraging the power of the innate immune system. AFM13 is Affimed’s most advanced ICE® clinical program, and it is currently being evaluated as a monotherapy in a registration-directed trial in patients with relapsed/refractory peripheral T-cell lymphoma or transformed mycosis fungoides (REDIRECT). The study is actively recruiting and can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) using the identifier NCT04101331.

Affimed is currently studying AFM13 in combination with cord blood-derived allogeneic natural killer cells in cooperation with the MD Anderson Cancer Center in Houston. The investigator-sponsored Phase 1 study is preparing to administer a stable complex of AFM13 pre-mixed with

cord blood-derived allogeneic NK cells, the study can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) using the identifier NCT04074746.

### **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 is currently enrolling patients into a registration-directed study of AFM13 for CD30-positive relapsed/refractory peripheral T cell lymphoma and into a Phase 1/2a dose escalation/expansion study of AFM24 for the treatment of advanced EGFR-expressing solid tumors. For more information, please visit [www.affimed.com](http://www.affimed.com).

### **About The Leukemia & Lymphoma Society and [Therapy Acceleration Program® \(TAP\)](#)**

The Leukemia & Lymphoma Society® (LLS) is a global leader in the fight against cancer. The LLS mission: cure leukemia, lymphoma, multiple myeloma, and improve the quality of life of patients and their families. LLS TAP is a strategic initiative that builds business alliances and collaborations with biotechnology companies and academic researchers to identify potential breakthrough therapies with the potential to change the standard of care. LLS TAP funds late stage pre-clinical studies, and proof of concept or registrational clinical trials to help advance these more quickly along the drug development and approval pathway. To learn more, visit [www.LLS.org](http://www.LLS.org).

### **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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