PRESS RELEASE

Affimed Announces New Innate Cell Engager AFM28 Targeting CD123 to Treat Acute Myeloid Leukemia

- Derived from Affimed’s ROCK® platform, AFM28 binds selectively and with high affinity the surface antigens CD123 and CD16A
- AFM28 shows better killing of primary leukemic blasts in comparison to monoclonal antibodies which may lead to enhanced ADCC in patients
- In a preclinical toxicology study AFM28 was safe and well-tolerated and exhibited the expected pharmacodynamic activity
- The high affinity of AFM28 to CD16A is well suited for the combination with allogeneic NK cells
- The AFM28 program is planned to advance to an IND filing in the first half of 2022; a clinical study is expected to begin in the second half of 2022
- The clinical program will investigate AFM28 as treatment designed to address the needs of patients with Acute Myeloid Leukemia (AML) and other CD123+ myeloid malignancies, such as high-risk Myelodyplastic Syndrome (HR-MDS)

Heidelberg, Germany, November 4, 2021 – Affimed N.V. (Nasdaq: AFMD), a clinical-stage immuno-oncology company committed to giving patients back their innate ability to fight cancer, announced today that AFM28, its novel Innate Cell Engager (ICE®), is designed to treat patients with Acute Myeloid Leukemia (AML) and other CD123+ myeloid malignancies, such as high-risk myelodysplastic syndrome (MDS).

Affimed will describe AFM28 in a poster covering initial preclinical data at the upcoming ASH conference. The company plans to submit an IND application in the first half of 2022, and initiate a first-in-human study in the second half of 2022.

“Redirecting innate immune cells, particularly NK cells, to CD123 is highly attractive as a novel treatment strategy in AML, because CD123 is almost universally expressed on leukemic blasts and leukemic stem cells, and we know that efficient depletion of both these cell types is critical for inducing long-term remission. Further, NK cell-based therapies have been demonstrated to
be clinically active in AML,” said Arndt Schottelius, Chief Scientific Officer at Affimed. “We believe that engaging NK cells with our new ICE® AFM28 will enable new immunotherapeutic approaches to address the unmet needs in AML, either as monotherapy or in combination with adoptive NK cell therapy.”

AFM28 was developed on Affimed’s proprietary ROCK® platform and is a bispecific, tetravalent ICE® that targets CD16A on NK cells and macrophages as well as CD123 on leukemic cells and leukemic stem cells in AML. The high affinity to CD123 and to CD16A is initiating antibody-dependent cell-mediated cytotoxicity (ADCC) against CD123+ tumor cells. Preclinical data demonstrate that AFM28 induces tumor cell lysis more potently than conventional anti-CD123 antibodies, even at low CD123 expression. Further, AFM28 shows a 100-fold more potent NK cell activation in an ex vivo analysis, compared to Fc-enhanced IgG1 antibodies. In a preclinical toxicology study in cynomolgus monkey, AFM28 was safe and well-tolerated and exhibited the expected pharmacodynamic activity suggesting a good safety profile and the potential to eliminate CD123+ cells in vivo. Clinical investigation of AFM28 is planned as monotherapy and in combination with allogeneic NK cell therapy.

About Acute Myeloid Leukemia

Acute Myeloid Leukemia is the most common form of adult leukemia, with approximately 20,000 new cases diagnosed every year in the US alone. Despite recent advances in the management of hematological malignancies, progress in the treatment of AML has lagged behind and the overall outcome for patients remains very poor; while complete remission (CR) can be initially achieved in most patients, the majority of patients become primary refractory or relapse within 1 year. Treatment options for these patients are very limited, and the prognosis is dismal with 1-year and 5-year overall survival (OS) of 29% and 11%, respectively. Novel treatments that prevent relapse and are effective in relapsed / refractory disease constitute a major unmet need.

About AFM28

AFM28, a tetravalent, bispecific CD123- and CD16A-binding innate cell engager (ICE®) developed on Affimed’s ROCK® platform, is designed to bring a new immunotherapeutic approach to patients with CD123+ myeloid malignancies, including Acute Myeloid Leukemia and Myelodysplastic Syndrome (MDS). It engages NK cells to initiate tumor cell killing via antibody-dependent cellular cytotoxicity (ADCC), even at low CD123 expression levels. Clinical development is planned as both single-agent and within a novel combination regimen aimed at bringing an NK cell-based mode of actions to patients with CD123+ myeloid disease.

About Affimed N.V.

Affimed (Nasdaq: AFMD) is a clinical-stage immuno-oncology company committed to give patients back their innate ability to fight cancer by actualizing the untapped potential of the
innate immune system. The company’s proprietary ROCK® platform enables a tumor-targeted approach to recognize and kill a range of hematologic and solid tumors, enabling a broad pipeline of wholly owned and partnered single agent and combination therapy programs. The ROCK® platform predictably generates customized innate cell engager (ICE®) molecules, which use patients’ immune cells to destroy tumor cells. This innovative approach enabled Affimed to become the first company with a clinical-stage ICE®. Headquartered in Heidelberg, Germany, with offices in New York, NY, Affimed is led by an experienced team of biotechnology and pharmaceutical leaders united by a bold vision to stop cancer from ever derailing patients’ lives. For more about the company’s people, pipeline, and partners, please visit: 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 potential of AFM13, AFM24, AFM28 and our other product candidates, 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 SEC. 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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