



Affimed Announces Dosing of First Patient in Phase 1 Clinical Trial of Cord Blood-derived Natural Killer Cells in Combination with the Innate Cell Engager AFM13

- *First of its kind clinical study combining a Natural Killer (NK) cell product with an innate cell engager (ICE®)*
- *Study investigates NK cells preloaded with AFM13, followed by subsequent weekly treatment with AFM13 monotherapy in patients with recurrent or refractory (r/r) CD30-positive lymphomas*
- *Stable preloading of AFM13 on NK cells enabled through high affinity binding to CD16A*

Heidelberg, Germany, October 6, 2020 – Affimed N.V. (Nasdaq: AFMD), a clinical-stage immunology company committed to giving patients back their innate ability to fight cancer, today announced that the first patient was successfully dosed with allogeneic cord blood-derived natural killer (cbNK) cells preloaded with AFM13 and has moved on to the AFM13 monotherapy phase of the treatment cycle. This therapy was developed through a research collaboration with The University of Texas MD Anderson Cancer Center.

This is the first in human study to combine an NK cell product with an antibody whose primary mechanism is designed to specifically bind and activate NK cells and tumors cells in a bispecific fashion. This novel combination approach could lay the groundwork for future cellular therapy combinations with Affimed ICE® constructs.

“Engaging the innate immune system is a novel and promising therapeutic approach in oncology and our ICE® products are designed to tap into this, which, thus far, has largely remained untapped in this field,” said Dr. Andreas Harstrick, Chief Medical Officer at Affimed. “Pre-loading innate immune cells with an ICE® takes this idea a step further and potentially intensifies the treatment’s effect, especially in patients who have an impaired immune system or low NK cell numbers.”

An NK cell armed with AFM13 is designed to direct NK cells to the tumor site in order to target cancer cells. Pursuant to the study design, after dosing with the preloaded NK cells, AFM13 is

subsequently administered as monotherapy in order to maintain the activation of the infused cbNK cells and engage the patients' own innate immune system (NK cells and macrophages), a distinct feature of Affimed's ICE® products.

Further Study Background

Although larger numbers of NK cells in patients is associated with better outcomes, the adoptive transfer of non-targeted NK cells has shown only limited clinical benefit. Target recognition of cancers by NK cells remains a substantial barrier to broad application of an NK cell therapy. In preclinical models, combining AFM13 with adoptive NK cell transfer has been shown to enhance the efficacy of NK cells. AFM13 exhibited a much longer binding to CD16A on NK cells as compared to CD30 binding monoclonal antibodies, both wildtype and ADCC enhanced, forming the basis to produce a stable AFM13 pre-loaded NK cell product.

The study, which aims to enroll approximately 30 patients, is an investigator-initiated study at MD Anderson. The study is an open-label, non-randomized, single-center, dose escalation trial to evaluate the combination of AFM13 with cord blood-derived NK cells in adult patients with recurrent/refractory CD30-positive lymphomas. The primary objective of the study is to establish the safety and the recommended Phase 2 dose of AFM13-preloaded cbNK cells, followed by weekly treatment with intravenous AFM13. Secondary objectives include assessing the overall, complete and partial response rates. More details about the study can be found at www.clinicaltrials.gov using the identifier NCT04074746.

About AFM13

AFM13 is a first-in-class CD30/CD16A ROCK®-derived bispecific innate cell engager (ICE®) 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 (REDIRECT). The study is actively recruiting and can be found at www.clinicaltrials.gov using the identifier NCT04101331.

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.

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, 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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