



## **Affimed Initiates Patient Recruitment for a Phase 1/2a Trial of Innate Cell Engager AFM24 in Combination with Roche's Anti-PD-L1 Checkpoint Inhibitor Atezolizumab**

**Heidelberg, Germany, December 08, 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 the initiation of patient recruitment for the open-label, multi-center phase 1/2a study evaluating the safety, tolerability, pharmacokinetics and efficacy of the innate cell engager (ICE®) AFM24 in combination with Roche's atezolizumab, an anti-PD-L1 checkpoint inhibitor. AFM24 is Affimed's tetravalent, bispecific epidermal growth factor receptor (EGFR)- and CD16A-targeting ICE®, developed for the treatment of patients with solid tumors.

“Natural killer cells, which are part of the innate immune system, have the ability to recognise cancer cells. AFM24, a novel immunotherapy, aims to redirect and engage these natural killer cells by linking them to a protein called EGFR, which is expressed on many solid tumours, to increase their tumour killing potency,” said Dr Juanita Suzanne Lopez, Consultant Medical Oncologist at The Royal Marsden and Clinical Researcher at The Institute of Cancer Research, London and principal investigator for the study. “By combining AFM24 with an immune checkpoint inhibitor, we aim to activate both the innate and the adaptive immune system to improve patient outcomes. This approach has exciting potential for a broad range of tumour types, including lung, gastroesophageal, liver and pancreatic cancers.”

The study will consist of two parts. The first part is a dose escalation phase, aiming to determine the maximum tolerated dose/recommended phase 2 dose of AFM24 in combination with atezolizumab. In the second part, the expansion phase (phase 2a), the goal is to collect preliminary evidence of efficacy as well as to confirm the safety of the therapeutic combination. The trial will include patients with solid tumors, including non-small cell lung cancer (NSCLC, EGFR-wildtype), gastric- and gastroesophageal junction adenocarcinoma and pancreatic/hepatocellular/biliary tract cancer. All patients have failed ≥1 prior line of treatment before receiving the combination of AFM24 and atezolizumab.

“Initiation of this trial is an important step in our three-pronged approach for developing our ICE® molecules. We are driven by the biology of the targets and cancer indications to identify the right approach evaluating AFM24 in monotherapy, together with NK cells or immunotherapy,” said Dr.

Andreas Harstrick, CMO at Affimed. “We believe that the combination with anti-PD-L1 has the potential to provide benefits to a broad population of cancer patients.”

Preclinical studies of AFM24 have demonstrated a good safety profile and anti-tumor activity. AFM24 monotherapy is currently being investigated in adult patients with advanced EGFR-positive solid malignancies in an open-label, non-randomized, multi-center, multiple ascending dose escalation/expansion study.

A Phase 1b study of another ICE<sup>®</sup>, AFM13, in combination with the anti-PD-1 checkpoint inhibitor pembrolizumab has been published in *Blood* last year (Bartlett et al. *Blood* 2020, 136 (21): 2401–09), demonstrating an objective response rate (ORR) of 88% and a complete response (CR) rate of 46% at the recommended dose level in patients with relapsed/refractory Hodgkin lymphoma. The high ORR and CR rate in this proof-of-concept study were considered highly encouraging for the combination of the ICE<sup>®</sup> with a checkpoint inhibitor and indicated that the activation of innate immunity has the potential to improve current therapies.

### **About AFM24**

AFM24 is a tetravalent, bispecific innate cell engager (ICE<sup>®</sup>) that activates the innate immune system by binding to CD16A on innate immune cells and EGFR, a protein widely expressed on solid tumors, to kill cancer cells. Generated by Affimed’s fit-for-purpose ROCK<sup>®</sup> platform, AFM24 represents a distinctive mechanism of action that uses EGFR as a docking site to engage innate immune cells for tumor cell killing through antibody-dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis.

In addition to the AFM24-102 study presented here (NCT05109442), Affimed is evaluating AFM24 as a monotherapy (AFM24-101) for patients with advanced EGFR-expressing solid malignancies whose disease has progressed after treatment with previous anticancer therapies. The first-in-human Phase 1/2a open-label, non-randomized, multi-center, multiple ascending dose escalation and expansion study and can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) using the identifier NCT04259450.

Furthermore, Affimed and NKGen Biotech have initiated a Phase 1/2a study (AFM24-103) in November 2021, evaluating AFM24 in combination with SNK01, NKGen Biotech’s NK cell product (NCT05099549).

### **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 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](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 intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, the potential of Affimed's ROCK® platform, ICE® product candidates and AFM24, NKGen Biotech's NK cell technology and SNK01, and preclinical development and clinical trials, 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 neither company assumes any obligation to update these forward-looking statements, even if new information becomes available in the future.

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