



PRESS RELEASE

Affimed Presents Final Data Demonstrating Safety and Efficacy of AFM13 Phase 2 REDIRECT Study in Patients with Heavily Pretreated Relapsed or Refractory Peripheral T Cell Lymphoma at the American Association for Cancer Research Annual Meeting 2023

- AFM13 demonstrated robust activity on the primary end point with an objective response rate (ORR) of 32.4% and 10.2% complete response rate (CR) in Intent to Treat (ITT) population
- Patients with Angioimmunoblastic T cell lymphoma (AITL), one of the most frequent subtypes of peripheral T Cell Lymphoma (PTCL), exhibited the highest ORR (53.3%) and CR (26.7%)
- Other measures of efficacy included median duration of response (DoR) of 2.3 months, median progression free survival (PFS) of 3.5 months and median overall survival (OS) of 13.8 months in advanced stage relapsed / refractory (r/r) PTCL patients
- Comparable response rates observed in patients with high and low CD30 expression levels and regardless of prior brentuximab vedotin treatment
- AFM13 exhibited a tolerable safety profile; most common treatment-emergent adverse events (TEAEs) were infusion-related reactions (IRR) in 25% of patients and neutropenia in 10% of patients
- Affimed plans to focus future investment in PTCL on the combination of AFM13 with AB-101 NK cells

Heidelberg, Germany, April 16, 2023 – Affimed N.V. (Nasdaq: AFMD) (“Affimed”, or the “Company”), a clinical-stage immuno-oncology company committed to giving patients back their innate ability to fight cancer, today provided the final results from its phase 2 REDIRECT study investigating its innate cell engager (ICE®) AFM13 monotherapy in patients with heavily pretreated advanced-stage r/r PTCL. The results are being presented at the American Association for Cancer Research (AACR) Annual Meeting by Dr. Won Seog Kim, Professor of Hematology-Oncology at Samsung Medical Center in Seoul and a principal investigator for the study, and establishes that AFM13 monotherapy showed efficacy in the treatment of relapsed/refractory peripheral T cell lymphoma (r/r PTCL) patients with a differentiated safety profile.

Primary efficacy measures include an ORR of 32.4% and a CR rate of 10.2%. Key secondary and exploratory outcome measures include safety, durability of response, progression free survival and overall survival.

Median DoR was 2.3 months, median PFS was 3.5 months and median OS was 13.8 months. PFS and OS were comparable with currently approved therapies for r/r PTCL. Of all PTCL subsets, patients with AITL exhibited the highest ORR (53.3%) and CR (26.7%) with DoR not meaningfully different across the various subsets.

The safety profile of AFM13 was well managed and consistent with previously reported data of prior and ongoing clinical studies with AFM13. Most common TEAEs were IRR (25%), neutropenia (10.2%) and pyrexia (8.3%). No AFM13-related fatal toxicities were observed.

“I’m very proud of the REDIRECT results demonstrating that innate immune cell engagement through our ICE® AFM13 has effective single agent activity with a differentiated safety profile. These data substantiate the next step towards further development of AFM13 in PTCL” said Dr. Adi Hoess, Chief Executive Officer at Affimed. “Our parallel study investigating AFM13 in combination with allogeneic NK cells shows that such a combination can achieve remarkable clinical outcomes for patients with CD30-positive lymphomas. We believe we can build on the already meaningful activity through the combination with Artiva’s NK Cell (AB-101) giving these vastly underserved patients a meaningful treatment option.”

“The strong activity of AFM13 in heavily pretreated patients with peripheral T cell Lymphoma is very encouraging and, coupled with the favorable safety profile, provides a rationale for further clinical development of the agent in PTCL. PTCL is a disease that can be challenging to treat with an urgent need for new mechanisms, as there are very few options today. AFM13 holds promise to address the gap in current treatment options,” said Dr. Won Seog Kim.

About REDIRECT

REDIRECT is a registration-directed phase 2 open-label, multicenter, global study investigating the efficacy and safety of AFM13 monotherapy in patients with CD30-positive r/r PTCL. The primary outcome measure was the objective response rate (ORR) following treatment with AFM13 as measured by an independent review committee (IRC) by FDG-PET. Secondary and exploratory outcome measures included DoR, PFS, OS, the safety of AFM13 as well as pharmacokinetics and immunogenicity of AFM13. In the trial, 108 patients received treatment with AFM13 as weekly intravenous infusions of 200 mg for the duration of the trial participation. Disease assessment was conducted at screenings every 8 weeks for the first 2 assessments and every 12 weeks thereafter.

About Peripheral T cell Lymphomas

Peripheral T cell lymphomas are highly aggressive and one of the most difficult to treat forms of lymphoma with very poor prognosis for patients, especially in later lines of therapy. Based on the compelling data seen in Hodgkin lymphoma for the combination of AFM13 with cord blood-derived NK cells in the AFM13-104 study, the Company believes that the combination with NK cells has a higher probability to deliver increased anti-tumor activity and a more durable clinical benefit to address the unmet need in this patient population.

Accordingly, Affimed will focus investment on clinical development in the combination of AFM13 with Artiva’s AB-101 NK cell product and does not intend to pursue an accelerated approval for AFM13 monotherapy in PTCL.

Details of the oral presentation are as follows:

Title: A phase 2 study of AFM13 in patients with CD30-positive relapsed or refractory (R/R) peripheral T cell lymphoma (PTCL)

Session: Novel Clinical Trials for Hematological Malignancies

Presentation Date & Time: Sunday April 16, 3:00 – 5:00 p.m. EDT

Location: Orange County Convention Center, Orlando, Florida, Valencia A

The presentation/abstract is accessible through the following link: <https://www.affimed.com/news-events>

About AFM13

AFM13 is a first-in-class innate cell engager (ICE®) that uniquely activates the innate immune system to destroy CD30-positive hematologic tumors. AFM13 induces specific and selective killing of CD30-positive tumor cells, leveraging the power of the innate immune system by engaging and activating natural killer (NK) cells and macrophages. AFM13 is Affimed's most advanced ICE® clinical program and is currently being evaluated as monotherapy in a registration-directed trial in patients with relapsed/refractory peripheral T cell lymphoma (REDIRECT). Additional details can be found at www.clinicaltrials.gov (NCT04101331). The study achieved an ORR of 32.4% demonstrating anti-tumor activity with a DOR of 2.3 months and a well-managed safety profile. AFM13 is a tetravalent bispecific innate cell engager designed to act as a bridge between the innate immune cells and the tumor creating the necessary proximity for the innate immune cells to specifically destroy the tumor cells.

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.

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 the Company’s intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, the potential of AFM13, AFM24, AFM28 and the Company’s other product candidates, the value of its ROCK® platform, its ongoing and planned preclinical development and clinical trials, its collaborations and development of its products in combination with other therapies, the timing of and its ability to make regulatory filings and obtain and maintain regulatory approvals for its product candidates, its intellectual property position, its collaboration activities, its ability to develop commercial functions, clinical trial data, its results of operations, cash needs, financial condition, liquidity, prospects, future transactions, growth and strategies, the industry in which it operates, the macroeconomic trends that may affect the industry or the Company, such as the instability in the banking sector experienced in the first quarter of 2023, impacts of the COVID-19 pandemic, the benefits to Affimed of orphan drug designation, the impact on its business by political events, war, terrorism, business interruptions and other geopolitical events and uncertainties, such as the Russia-Ukraine conflict, the fact that the current clinical data of AFM13 in combination with NK cell therapy is based on AFM13 precomplexed with fresh allogeneic cord blood-derived NK cells from The University of Texas MD Anderson Cancer Center, as opposed to Artiva’s AB-101 and other uncertainties and 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 the Company assumes no obligation to update these forward-looking statements, even if new information becomes available in the future.

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