



Affimed Announces U.S. Registrational Pathway and Updated Clinical Development Plan for AFM13 at R&D Day

- Company to Pursue Registrational Pathway for Lead Agent AFM13 Monotherapy in Patients with Peripheral T Cell Lymphoma with Potential for Accelerated Approval -

- Clinical Studies for AFM13 in Combination with anti-PD1 Antibody Agent and with Adoptive NK Cell Transfer in CD30-Positive Lymphomas Could Lead to Expanded Market Opportunities -

Heidelberg, Germany, December 7, 2018 - Affimed N.V. (Nasdaq: AFMD), a clinical stage biopharmaceutical company committed to improving patient outcomes through the power of the innate immune system, announced its registrational pathway, updated clinical development plans and the estimated market opportunity for the Company's lead candidate AFM13 – a first-in-class innate cell engager – at its Research & Development Day in New York City.

Affimed plans to initiate a Phase 2 study evaluating the safety and efficacy of AFM13 as monotherapy in relapsed or refractory peripheral T cell lymphoma (PTCL) and transformed mycosis fungoides (TMF), a subset of cutaneous T cell lymphoma (CTCL) in the first half of 2019. Based on preliminary feedback from the U.S. Food and Drug Administration (FDA) and on [data](#) presented at this week's America Society of Hematology (ASH) Annual Meeting, Affimed believes that results from an open-label, single-arm Phase 2 study could form the basis for a Biologics License Application (BLA) submission and support an accelerated approval, given the unmet medical need for safe and effective new treatments in this hard-to-treat population.

"We believe that the clinical development plan shared today for AFM13 provides potential for accelerated approval and helps to lay the groundwork for further investigations of CD16A innate immune engagers," said Dr. Adi Hoess, Affimed's CEO. "Through our fit-for-purpose ROCK® platform, we continue to generate novel engagers, like AFM13, to broaden our leadership in innate immunity. We look forward to continuing this important work to enhance current immunoncology approaches, with the ultimate goal of giving patients back the body's innate ability to fight cancer."

The broader clinical development strategy for AFM13 includes expanding into other CD30-positive lymphoma indications and additional treatment lines with significant unmet need. In collaboration with strategic partners, Affimed plans to investigate AFM13 in combination with other immunotherapy agents, such as an anti-PD-1/PD-L1 antibody agent and with adoptive NK cell transfer.

“AFM13’s clinical profile to date is very encouraging,” said Dr. Leila Alland, Chief Medical Officer of Affimed. “The recently presented data at ASH increase our confidence that AFM13 holds significant therapeutic value for patients with CD30-positive lymphoma. Our team is looking forward to initiating the registrational study for AFM13 in the first half of 2019 and it is our commitment to develop this potential treatment for patients as quickly as possible.”

“Our market research suggests a sizable near-term commercial opportunity for AFM13 with an estimated initial eligible population of about 2,500 patients per year with relapsed or refractory PTCL in the U.S.,” said Denise Mueller, Head of Commercial Strategy and Business Development of Affimed. “We believe our clinical development plan for AFM13 combination therapies will further expand the market potential of AFM13 in CD30-positive lymphoma indications such as Hodgkin lymphoma and T cell lymphoma.”

Additional Research & Development Day Program Highlights

Dr. Steven M. Horwitz, Associate Attending, Division of Hematologic Oncology, Memorial Sloan Kettering Cancer Center, presented on the current treatment landscape and unmet needs in patients with peripheral and cutaneous T cell lymphomas and Hodgkin lymphoma.

Dr. Ahmed Sawas, Assistant Professor of Medicine, Columbia University College of Physicians and Surgeons and the New York-Presbyterian Hospital, Principal Investigator of the investigator-sponsored Phase 1b/2a trial of AFM13 in CD30-positive lymphoma with cutaneous manifestation led by Columbia University Medical Center, discussed data from the study recently presented at the ASH Annual Meeting.

Affimed reviewed the updated data from the Phase 1b study of AFM13 as a combination therapy with Merck’s anti-PD-1 antibody Keytruda® (pembrolizumab) in relapsed or refractory Hodgkin lymphoma (HL) patients that was presented at the ASH Annual Meeting.

Dr. Yago Nieto, Professor of Medicine, Department of Stem Cell Transplantation, The University of Texas MD Anderson Cancer Center, discussed data from the preclinical research of cord blood derived natural killer cells loaded with AFM13 as off-the-shelf cell therapy for CD30-positive malignancies conducted under Affimed’s sponsored research collaboration with MD Anderson. He concluded that the encouraging data observed in this study, which was featured in an oral

presentation at the ASH Annual Meeting, provide a strong rationale for clinically investigating the strategy of an off-the-shelf adoptive immunotherapy with AFM13-loaded CB-NK cells in patients with relapsed/refractory CD30+ malignancies. Dr. Nieto outlined plans to conduct a clinical study in patients with CD30-positive lymphoma.

Webcast Information

The archived webcast and slides of the presentation are available under the “News & Events” section of Affimed’s website at <http://www.affimed.com/news-events/> and will be available for 30 days following the event.

About AFM13

AFM13 is a first-in-class tetravalent, bispecific NK cell engager that specifically binds to CD30 on tumor cells and to CD16A on NK cells. AFM13 is being developed in Hodgkin lymphoma (HL) and in other CD30-positive lymphomas. AFM13 has shown a favorable safety profile and signs of therapeutic efficacy in a monotherapy setting in studies in HL and CD30-positive lymphoma with cutaneous manifestation. In addition, data from a combination study of AFM13 with Merck’s anti-PD-1 antibody Keytruda® (pembrolizumab) supports proof of principle for the combination of NK cell engagement with checkpoint inhibition. AFM13 has been granted orphan drug designation by the U.S. Food and Drug Administration.

About Affimed’s ROCK® Platform

Affimed’s proprietary, versatile and modular ROCK® (Redirected Optimized Cell Killing) platform enables the generation of first-in-class, tetravalent, multi-specific immune cell engagers. Based on its modularity, ROCK® allows for antibody engineering of highly customizable innate immune cell and T cell engagers to generate clinical candidates tailored to multiple disease indications and settings, including generation of molecules against validated oncology targets to address the limitations of existing treatments of hematologic and solid tumors.

About Affimed N.V.

Affimed (Nasdaq: AFMD) is a clinical stage biopharmaceutical company which engineers targeted immunotherapies, seeking to improve patient outcomes through the power of innate immunity. Affimed’s fit-for-purpose ROCK® platform allows innate immune engagers to be designed for specific patient populations. We are developing single and combination therapies to treat cancers. 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 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, expectations regarding 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 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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