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Affimed Presents Data from Phase 1b Combination Study of AFM13 with Pembrolizumab at ASH

Completed dose-escalation shows combination of AFM13 and pembrolizumab is well-tolerated; 3-month ORR compares favorably to historical ORR of pembrolizumab alone

Additional preclinical data presented on BCMA-targeting NK cell engager AFM26

Heidelberg, Germany, December 11, 2017 - Affimed N.V. (Nasdaq: AFMD), a clinical stage biopharmaceutical company focused on discovering and developing highly targeted cancer immunotherapies, today announced the presentation of clinical and preclinical data on its tetravalent, bispecific natural killer (NK) cell engagers at the 59th American Society of Hematology (ASH) Annual Meeting and Exposition 2017 in Atlanta, GA.

Phase 1b study of AFM13 in combination with pembrolizumab (NCT02665650)

A poster presentation featured data from the completed dose-escalation part of Affimed's ongoing Phase 1b study to evaluate the safety and tolerability of the combination of the Company's lead product candidate AFM13 with pembrolizumab (Keytruda®) as salvage therapy after failure of standard therapies including brentuximab vedotin (BV) in relapsed or refractory (R/R) Hodgkin lymphoma (HL). Overall, the combination was well-tolerated and the 3-month ORR of 83% (5/6) compares favorably to historical ORR of pembrolizumab alone in a similar patient population (58-63%).

"We are pleased with this early data from our ongoing Phase 1b trial which demonstrate that AFM13 can safely be administered in combination with Keytruda," said Dr. Adi Hoess, CEO of Affimed. "Importantly, we also report promising ORR data in patients which have failed prior treatments including ASCT and BV. While we have reported encouraging monotherapy data from earlier trials in the past showing that AFM13 is able to induce remission in heavily pretreated lymphoma patients, we believe that the combination with Keytruda has great potential to provide additional benefit to patients. These data mark significant progress towards a safe and effective NK cell engager-based cancer immunotherapy. With the extension cohort accruing, we look forward to continuing on this path."

Patients received escalating doses of AFM13 in combination with pembrolizumab at a flat dose of 200 mg administered every 3 weeks following the classical 3+3 design. Recruitment now continues into an extension cohort at the highest dose level explored during dose escalation. Response assessment is performed every 12 weeks by PET/CT according to the Lugano Classification Revised Staging System for malignant lymphoma.

Safety Results

Three patients were enrolled into dose levels 1 (0.5 mg/kg) and 2 (1.5 mg/kg), respectively, and six patients were enrolled into dose level 3 (7.0 mg/kg). One dose-limiting toxicity (DLT) was observed in cohort 3, which was a repeated grade 2 infusion-related reaction (IRR), leading to discontinuation of AFM13 treatment. This event classified as a DLT according to the protocol definition. No additional DLTs occurred. The dose extension cohort has been initiated with the highest dose explored during dose escalation (7.0 mg/kg).

Most of the adverse events (AEs) observed were mild to moderate in nature and were manageable with standard of care. The most frequently observed AEs were IRRs (83%), nausea (42%), diarrhea (33%), headache (33%), pyrexia (33%) and rash (33%). Most of these events were of grade 1 or 2 severity. There was a total of four grade 3 AEs observed in the study with three events being deemed at least possibly related to both AFM13 and pembrolizumab: grade 3 IRR, grade 3 nausea and grade 3 vomiting. The remaining grade 3 AE of a duodenal ulcer was assessed as not related to either study treatment. The maximum-tolerated dose (MTD) was not reached.

Efficacy Results

Three-month metabolic responses were reported based on both local and independent assessment. By local assessment, in cohort 1, two Partial Metabolic Responses (PmRs) and one Progressive Metabolic Disease (PmD) were observed. In cohort 2, one Complete Metabolic Response (CmR), one PmR and one PmD were observed. In cohort 3, five PmRs and one PmD were observed by both local and independent assessments. This ORR of 83% (5/6) compared favorably to the historical ORR of pembrolizumab as monotherapy in R/R HL patients who were post autologous stem cell transplantation (ASCT) or ineligible for ASCT and have failed BV (58-63%). Additionally, a deepening of response was reported where a single case of PmR was converted into CmR at the 6-month assessment (independent assessment). Based on the risk/benefit analysis and recommendation by an independent data review committee (DRC) the extension cohort is currently recruiting.

Poster Information

Ansell et al.: A Phase 1 Study Investigating the Combination of AFM13 and the Monoclonal Anti-PD-1 Antibody Pembrolizumab in Patients with Relapsed/Refractory Hodgkin Lymphoma after Brentuximab Vedotin Failure: Data from the Dose Escalation Part of the Study (Abstract #1522)

AFM26 effectively induces killing of multiple myeloma cells *in vitro*

In a second poster presentation, preclinical data on AFM26, Affimed's B-cell maturation antigen (BCMA)/CD16A-targeting antibody were reported. Standard of care in first line treatment of multiple myeloma (MM) in eligible patients, high dose melphalan combined with ASCT, fails to eradicate minimal residual disease (MRD) in the majority of patients, ultimately leading to disease relapse.

AFM26 is designed to address the significant medical need of achieving sustained MRD negativity in MM by selectively engaging NK cells to induce myeloma cell lysis through its high-affinity bivalent binding to the key activating receptor CD16A. Thus, AFM26 can be used to "arm" NK cells for effective killing of myeloma cells.

Employing a wide range of functional assays, the data presented at ASH corroborated earlier studies, demonstrating that AFM26 induces autologous NK cell-mediated lysis of primary myeloma cells in a manner strictly dependent on target cell contact. In particular, AFM26 induces NK cell cytotoxicity towards cells expressing very low surface levels of BCMA, suggesting the potential for broad and deep anti-MM activity. Moreover, AFM26 binds with high affinity to NK cells in the presence of patient-derived IgG1 paraprotein, confirming that AFM26 is less prone to interference by high levels of circulating serum IgG compared to Fc-based antibodies. In addition, AFM26 possesses prolonged NK cell retention times and induces markedly lower levels of pro-inflammatory cytokines in peripheral blood mononuclear cell (PBMC) cultures in the presence of target cells compared to BCMA-directed T cell-activating approaches. In contrast to other monoclonal antibodies (mAbs) developed as MM therapies such as daratumumab and elotuzumab, AFM26 does not confer target-independent NK cell activation or NK cell depletion.

Due to their early reconstitution following ASCT and their ability to rapidly destroy malignant cells through direct cytotoxicity, NK cells are promising effector cells to target MRD in this setting. AFM26's safety profile anticipated based on preclinical data suggests suitability for enhancing the cytotoxicity of endogenous NK cells as well as adoptively transferred NK cells. Redirecting NK cells through AFM26 may therefore offer an effective treatment option for MM patients early after or in conjunction with ASCT. Thus, AFM26 is well-differentiated from other mAbs and a promising therapeutic candidate to address the unmet medical need of eradicating MRD in MM.

Poster Information

Gantke et al.: AFM26 – Targeting B Cell Maturation Antigen (BCMA) for NK Cell-Mediated Immunotherapy of Multiple Myeloma (Abstract #3082)

About Affimed's NK cell engagers

Affimed has developed a novel technology platform of NK cell-engaging antibodies to overcome the ability of tumor cells to evade immune recognition. Affimed's NK cell engagers are tetravalent (four binding domains) and bispecific (targeting two cell types, NK and tumor cell). Affimed has selected CD16A, a key activating receptor as NK cell target, allowing for high affinity and high specificity binding of target cells even with low target expression. Binding to CD16A redirects NK cells to recognize the tumor cell, triggering a signal cascade that leads to the destruction of tumor cells. Affimed has developed a pipeline of preclinical and clinical product candidates designed to address the medical need in hematologic and solid tumors as mono- and combination therapies.

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+ lymphoma with cutaneous manifestation. In addition, early data from a combination study of AFM13 with Merck's anti-PD1 antibody Keytruda® (pembrolizumab) supports proof of principle for the combination of NK cell engagement with checkpoint inhibition.

About AFM26

AFM26 is a first-in-class tetravalent bispecific NK cell engager that specifically binds to B-cell maturation antigen (BCMA) on myeloma cells and to CD16A on NK cells. AFM26 is being developed in multiple myeloma (MM) and offers a differentiated mode of action, targeting cells expressing very low levels of BCMA, conferring NK cell cytotoxicity without depleting NK cells, eliciting lower cytokine release compared to T cell-activating approaches and with NK cell binding largely unaffected by IgG competition. These unique features could position AFM26 in patients receiving autologous stem cell transplant (ASCT) at or shortly after transplant, a period in which no treatment is currently available. AFM6 is currently in preclinical development.

About Affimed N.V.

Affimed (Nasdaq: AFMD) engineers targeted immunotherapies, seeking to cure patients by harnessing the power of innate and adaptive immunity (NK and T cells). We are developing single and combination therapies to treat cancers and other life-threatening diseases. 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, 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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