Affimed Highlights Further Data on AFM13, a Bispecific CD30/CD16A TandAb in Development to Treat Hodgkin Lymphoma, at the 2014 AACR Annual Meeting

Phase 1 trial showed that AFM13 has a favorable safety profile and activity in terms of pharmacodynamics and tumor response

Heidelberg, Germany, April 10, 2014 - Affimed Therapeutics AG announced today further results from its phase 1 clinical trial of AFM13 as monotherapy for the treatment of patients with advanced relapsing/refractory (R/R) Hodgkin lymphoma. AFM13 is a bispecific TandAb antibody recruiting host natural killer (NK) cells via its CD16A-binding domains to engage and kill CD30-positive malignant cells.

In the clinical phase 1 study, 28 heavily pretreated patients suffering from R/R Hodgkin lymphoma received infusions of AFM13 with increasing doses in the range of 0.01 mg/kg up to 7 mg/kg. AFM13 was administered once weekly over 4 weeks in the majority of the patients. Primary endpoints were safety and tolerability. Secondary endpoints were pharmacokinetics, pharmacodynamics and clinical efficacy. The data were presented by Max Topp, Professor of Medicine at the University of Wuerzburg, at the AACR Annual Meeting 2014, San Diego, CA, USA, on April 8, 2014. The presentation is being made available by AACR via Webcast.

Key Data from AFM13

- AFM13 binds selectively to NK cells through CD16A (FcγRIIIA); neutrophils carrying CD16B (FcγRIIIB) are not bound
- Cytotoxic potency of AFM13 is consistently higher than those of the Fc-enhanced and native anti-CD30 IgGs
- Each of the intravenously administered doses of AFM13 was considered safe and well tolerated, a maximum tolerated dose was not reached
- AFM13 treatment resulted in a significant increase of activated NK cells in peripheral blood, which was more pronounced at dose levels ≥ 1.5 mg/kg
- Soluble CD30 values decreased during treatment with AFM13; this effect was pronounced in patients receiving dose levels ≥ 1.5 mg/kg AFM13
- Pharmacokinetic data revealed a dose proportional increase of systemic exposure with a half-life of 10-22 hours
- Clinical activity was observed over all dose levels and included patients that received prior brentuximab vedotin. Clinical activity was more pronounced at higher dose levels, and all partial responses (PRs) were observed at doses ≥ 1.5 mg/kg

“The clinical phase 1 trial met its primary endpoint and demonstrated that AFM13 can be administered safely. Clear activity could be demonstrated with the potential to further maximize the effect by optimizing the dose regimen and extending the treatment duration,” said Jens-Peter Marschner, MD, Chief Medical Officer of Affimed. “These data are promising, in particular because there is no alternative treatment option for patients in this setting. A phase 2 study investigating an optimized dose regimen will be initiated this year.”

For further information please contact:

Affimed Therapeutics AG
Doris Sommer

Phone: +49 6221 65307-0
Fax: +49 6221 65307-77
E-Mail: d.sommer@affimed.com

MC Services AG
Anne Hennecke

Phone: +49 211 529252-22
Fax: +49 211 529252-29
E-Mail: anne.hennecke@mc-services.eu

About Affimed

Affimed Therapeutics AG develops cancer therapies that direct the immune system to eliminate tumor cells. Its next generation multifunctional antibodies (TandAbs®, FlexiBodies®) engage two of the most potent cytotoxic cells of the immune defense arsenal (T-cells or natural killer (NK) cells) and link them with high affinity and precision to a tumor cell, thus triggering an attack by the immune cell that ultimately results in the destruction of the tumor cell. The company is positioned in the promising and dynamic field of cancer immunotherapy with two fully owned TandAb products in clinical development. AFM13 targets CD30-positive malignancies, such as Hodgkin Lymphoma (HL). This program is co-funded by the Leukemia and Lymphoma Society (LLS). In a phase 1 study, AFM13 has demonstrated a promising profile in relapsing/refractory refractory HL patients and is expected to advance into phase 2 studies late 2014. AFM11 targets CD19-positive malignancies, such as Non-Hodgkin Lymphoma (NHL). A phase 1 study with AFM11 in refractory NHL patients is expected to start in the second quarter of 2014. In addition, the company has in preclinical development a program targeting solid tumors through the selective tumor target Epidermal Growth Factor Receptor, Variant III (EGFRvIII). For more information, please visit www.affimed.com.

About Affimed's platform technologies

Affimed develops TandAbs and FlexiBodies, both targeted immunotherapies, with the aim to provide new treatment options to patients. These therapies are characterized by strong efficacy and high specificity, combined with a favorable safety profile. The company has three proprietary platforms based on antibody variable domains:

- NK cell TandAbs – these are tetravalent, bi-functional molecules that recognize a specific biologic target and utilizing their second functionality, bind with high affinity to NK cells and thereby direct the NK cell to eliminate the cancer cell. Affimed's first-in-class candidate AFM13, which exploits this mode of action, has already shown a favorable safety profile and promising activity in a phase 1 clinical study.

- T cell TandAbs – these are tetravalent, bi-functional molecules that recognize a specific biologic target and utilizing their second functionality, bind with high affinity to T cells and thereby direct the T cell to eliminate the cancer cell. AFM11 belongs to this platform. It has been shown that a T cell engaging mechanism is effective in patients: in addition to very high response rates, none of the tumor cells appeared to have survived treatment, even using the most sensitive detection methods. Such “deep” responses and the removal of minimal residual disease may translate into better long-term outcome.
- Tri-specific molecules for dual targeting of tumor cells – these are tetravalent, tri-functional structures that can be designed to target two different antigens/epitopes on the tumor cell and with the third functionality bind with high affinity to either T cells or NK cells.