



Affimed Therapeutics AG receives FDA Orphan Drug Designation for AFM13 against Hodgkin lymphoma

Heidelberg, Germany, September 15, 2009 – Affimed Therapeutics AG announced today that the US Food and Drug Administration (FDA) has granted orphan drug designation to the human recombinant antibody AFM13 for the treatment of Hodgkin lymphoma. The designation entitles Affimed to seven-year market exclusivity in the US upon approval of this drug candidate. AFM13 is a novel, bispecific antibody based on Affimed's proprietary TandAb technology. TandAbs are tetravalent antibodies characterized by their ability to identify and selectively destroy tumour cells in the human body by binding target molecules on the surface of tumour cells and activating T-cells or natural killer cells (NK cells) simultaneously. Preclinical data has shown promising evidence for the efficacy of AFM13 in Hodgkin lymphoma. The initiation of the first clinical studies is expected to start in the first quarter of 2010.

Dr. Rolf Günther, CEO of Affimed, commented: „Our promising preclinical data with AFM 13 convinced the FDA experts of the strong potential of our TandAb technology for the treatment of relapsed or refractory Hodgkin lymphoma where only limited treatment options exist. The positive decision on the part of the regulatory authority confirms the great, unmet medical need for new therapeutic approaches in this indication. Up to 10.000 people could benefit from those new therapies in the US approximately per year. Given the planned initiation of the first clinical trials with AFM 13 in the beginning of 2010, the orphan drug designation is a very important signal for the further successful global development of our lead product.“

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About Hodgkin lymphoma:

Hodgkin lymphoma is a malignant type of cancer targeting the lymphatic system, with the highest incidence among those aged between 20-40 years, and over 70 years. According to estimates by the American Cancer Society, Hodgkin lymphoma has a yearly incidence in 8,500 patients in the US alone. Despite the strong potential for recovery at the early stage of the disease, only insufficient therapeutic approaches have so far been developed, particularly with regard to those patients who do not respond to aggressive chemo- and radiotherapy, or those who relapse. Due to the severe side effects and the toxicity of this combined chemo- and radiotherapy, there is a great medical need for new treatments.

About Affimed Therapeutics AG:

Affimed Therapeutics AG is a therapeutic antibody company developing novel therapies for the treatment of life threatening diseases, mainly cancer diseases like Non-Hodgkin and Hodgkin lymphoma. The company has developed a highly productive technology platform enabling the generation of unique antibody formats derived from three distinct human antibody libraries. Affimed's antibody formats include TandAbs and Flexibodies - two tetravalent, bispecific antibody formats that promise a superior pharmacological profile and increased therapeutic potential, compared to monoclonal antibodies. The company has built a maturing pipeline of therapeutic antibody programs. The first clinical studies for the lead product AFM13 for the treatment of Hodgkin-Lymphoma are expected in the beginning of 2010. Another advanced pre-clinical candidate is developed for the treatment of Non-Hodgkin lymphoma. Further antibody programs for the treatment of solid tumors and autoimmune diseases are in pre-clinical development. The private company Affimed is a spin-off of the German Cancer Research Center, with 27 employees based in Heidelberg.

Orphan Drug Designation:

The orphan drug designation is intended to support and advance companies in the development of efficient therapies for the treatment of rare diseases. For this purpose, the U.S. Food and Drug Administration (FDA) enacted the Orphan Drug Act in 1983 that was followed by the EU in 2000 issuing the "EG-Arzneimittel-Verordnung für seltene Leiden". The orphan drug designation is awarded to those compounds that have a potential therapeutic value for the treatment of rare diseases. These diseases affect fewer than 200,000 patients in the US and approximately 230,000 patients in Europe per year. The designation provides specific benefits, including research support, eligibility for protocol assistance and possible exemptions or reductions in certain regulatory fees during development or at the time of application for market approval. The orphan drug designation ensures participating companies a seven-year market exclusivity in the US upon approval.