



TeGenero AG receives EU-orphan drug designation for Humanized Agonistic Anti-CD28 Monoclonal Antibody TGN1412 for the treatment of B-CLL

Würzburg, Germany, March 11, 2005 – TeGenero AG announced today that its Humanized Agonistic Anti-CD28 Monoclonal Antibody TGN1412, which is currently in late-stage pre-clinical development, has received designation as orphan medicinal product from the European Medicines Agency (EMA) for the treatment of B-cell Chronic Lymphocytic Leukaemia, B-CLL. The decision of this positive opinion was announced after the March meeting of the Committee for Orphan Medicinal Products.

B-CLL is a rare, chronic and life-threatening leukaemic disease for which currently no curative treatment exists. The pathophysiology of B-CLL is closely linked to a pronounced dysfunction of the patients' T lymphocytes. According to the proposed therapeutic mode-of-action, enhanced activation of T lymphocytes by treatment with TeGenero's TGN1412 is expected to result in fewer infections and better control of the cancer.

"The designation reflects a high medical need for safe and efficacious new treatment options in B-CLL", says Dr. Thomas Hanke, Chief Scientific Officer of TeGenero. "Due to its novel mode-of-action, TGN1412 has the potential to provide a significant benefit to patients suffering from B-CLL, as demonstrated in recent pre-clinical studies."

The EMA orphan drug designation entitles TeGenero AG to exclusive marketing rights in the EU on TGN1412 for ten years following marketing approval and to protocol assistance by EMA in order to optimize TeGenero's drug development strategy in compliance with regulatory requirements.

About designation as orphan medicinal product

"Orphan drugs" are medicinal products used for rare, life-threatening diseases or chronically debilitating conditions where no other or no sufficient effective treatment exists. Benefits of designation as orphan medicinal product by the EMA include reduced fees for centralized activities as well as advice on the conduct of clinical trials. An orphan designation is not a marketing authorization, which can only be granted after the quality, safety and efficacy of the product have been demonstrated.

About TGN1412

TGN1412 is a Humanized Agonistic Anti-CD28 Monoclonal Antibody that is being developed by TeGenero AG for the treatment of autoimmune and oncological diseases including rheumatoid arthritis and B-CLL. It is in late-stage preclinical development with clinical trials anticipated to start in Q4, 2005.

About TeGenero AG

TeGenero AG is a privately held biopharmaceutical company dedicated to the development of innovative, highly effective and broadly applicable therapeutic drugs for the treatment of severe immunological disorders. The company was founded in 2000 and is located in Würzburg, Germany. Its supervisory board is chaired by Prof. Jürgen Drews and includes co-founder Prof. Thomas Hünig, University of Würzburg, and Prof. Patrick Baeuerle, Micromet AG. TeGenero's management consists of Dr. Benedikte Hatz, Chief Executive Officer, and Dr. Thomas Hanke, Chief Scientific Officer.

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