

MEDIA STATEMENT

PHILOGEN SPA RECEIVES ORPHAN DRUG DESIGNATION FOR THE TREATMENT OF SOFT TISSUE SARCOMA.

Siena, Italy, 28 October 2016

[Philogen S.p.A., a clinical-stage biotechnology company focused on discovering and developing innovative immunology and immuno-oncology protein therapeutics](#), announced that the European Commission (EC) has granted Orphan Drug Designation to L19TNF - a non-covalent trimer of tumor necrosis factor (TNF) fused to an antibody specific to the extra-domain B of fibronectin in single-chain variable fragment format - for the treatment of soft-tissue sarcoma.

Soft Tissue Sarcoma (STS) affects approximately 2.8 in 10,000 people in the EU and a recent statistic estimated 5-year survival rate of 58 % for patients suffering from STS within the EU.

The EC decision is based on a recommendation by the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP). Orphan Drug Designation is granted for medicinal products that are intended for the diagnosis, prevention or treatment of rare diseases affecting less than 5 in 10,000 people in the European Union (EU). The Orphan Medicinal Product status of L19TNF entails a number of incentives, including 10-year market exclusivity once the product receives marketing authorisation.

“We are very pleased to receive Orphan Drug Designation for L19TNF in soft tissue sarcoma.,” said Dr. Duccio Neri, co-founder and CEO of the Philogen group. “The initial clinical results with L19TNF are very promising and we look forward to continue the development of such an important drug”.

About L19TNF

L19TNF is a fully human antibody-based biopharmaceutical product, which allows for selective accumulation of the anti-cancer agent TNF in high concentrations at the site of disease.

The recruiting Phase Ib study (PH-L19TNFDXO-01/12; EudraCT 2012-000950-75) is assessing safety of the combination of doxorubicin and L19TNF in advanced solid tumours including patients with STS.

For additional information, visit: <http://www.philogen.com/en/news/>

About the Philogen group

Philogen is a clinical-stage biotechnology company engaged in the discovery and development of novel biopharmaceutical products. Philogen’s strategy is to deliver bioactive agents, for example cytokines or drugs to the site of disease using antibodies and ligands that specifically and efficiently target stromal antigens. This technology has generated a strong proprietary pipeline of clinical-stage products and also pre-clinical compounds in an array of disease indications. Philogen is headquartered in Siena, Italy, and has research activities at its subsidiary company Philochem in Zürich, Switzerland. Philogen is independently owned, and has signed agreements with several major pharmaceutical companies. For more information, please visit www.philogen.com
