

## **MEDIA STATEMENT**

### **Philogen Receives Orphan Drug Designation for the Treatment of Soft Tissue Sarcoma.**

Siena, Italy, January 08, 2019

Philogen S.p.A., a clinical-stage biotechnology company focused on discovering and developing innovative immunology and immuno-oncology protein therapeutics, announced that the US Food and Drug Administration (FDA) has granted Orphan Drug Designation status to Fibromun for the treatment of soft tissue sarcoma.

Fibromun is a fully human antibody-cytokine fusion protein consisting of the non-covalent trimer of tumor necrosis factor (TNF) fused to an antibody specific to the extra-domain B of fibronectin (L19) in single-chain variable fragment format. The antibody-TNF fusion protein selectively localizes to tumor lesions following systemic administration. The product is currently being studied in two pivotal studies: a Phase III clinical trial in Europe and a Phase IIb clinical trial in the US.

The Food and Drug Administration (FDA) grants Orphan Drug Designation according to section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for pharmaceutical products that are intended for the diagnosis, prevention or treatment of rare diseases affecting less than 200'000 American citizens. The Orphan Medicinal Product status of Fibromun entails a number of incentives, including 7-year market Orphan Drug Exclusivity (ODE).

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

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

### **About the Philogen Group**

Philogen is a Swiss-Italian 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](http://www.philogen.com)

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