

MEDIA STATEMENT

Philogen Receives Orphan Drug Designation for the Treatment of Melanoma.

Siena, Italy, 18 July 2018

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 Daromun for the treatment of melanoma stages IIb through IV.

Daromun is a combination product of two fully human antibody-cytokine fusion proteins consisting of the non-covalent trimer of tumor necrosis factor (TNF) and the immunomodulatory cytokine Interleukin 2 (IL2), both fused to an antibody specific to the extra-domain B of fibronectin (L19) in single-chain variable fragment format.

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 Daromun entails a number of incentives, including 7-year market Orphan Drug Exclusivity (ODE).

“We are very pleased to receive Orphan Drug Designation for Daromun in melanoma,” said Dr. Duccio Neri, co-founder and CEO of the Philogen group. “The initial clinical results with Daromun 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 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
