MEDIA STATEMENT

PHILOGEN ANNOUNCES AUTHORIZATION FROM FDA OF A PIVOTAL REGISTRATION TRIAL IN USA FOR THE TREATMENT OF RESECTABLE MELANOMA

Siena, Italy, 10/12/2017. Philogen S.p.A. (www.philogen.com), a privately owned biotechnology company, today announced approval by Food and Drugs Administration (FDA) of an IND for a Phase 3 registration trial with investigational melanoma drug DAROMUN (L19IL2 + L19TNF).

Philogen's pivotal trial will recruit in total 248 patients with fully resectable stage IIIB or IIIC melanoma. The study is currently already ongoing in three European countries (Italy, Germany and Poland), and is due to publish results in 2020.

"The approval by FDA to expand the study in USA underscores confidence on the safety and efficacy data shown in previous studies with this product, and provides hopes to melanoma patients not adequately served by current therapies" commented Philogen Chief Executive Duccio Neri.

DAROMUN is a Philogen's proprietary immunocytokine product, which is being developed as a neoadjuvant therapy, to be administered via intratumoral injections in stage IIIB/C melanoma patients, eligible for complete resection of all metastases and with at least one injectable cutaneous, sub-cutaneous or lymph node metastasis.

"DAROMUN combines a number of desirable characteristics such as good tolerability and efficacy that make it an exciting and promising immunotherapy for the treatment of resectable melanoma" commented Prof. Dr. Dario Neri, cofounder and president of the Scientific Advisory Board of Philogen.

The FDA-approved study will be led by principal investigator Jonathan S. Zager, MD, FACS, at Moffitt Cancer Center in Tampa, Florida, as the lead U.S. site. Dr. Zager is a world-reknown expert in melanoma and an international thought leader in intralesional treatment of resectable melanoma patients.

"Stage IIIB/C patients with resected primary melanoma are at a high risk of recurrence. We are very excited to start this trial of neoadjuvant use of DAROMUN, which holds promise to improve the outcome after surgery in these patients, hopefully extending the recurrence-free survival time," said Dr. Zager, Professor of Surgery and Senior Member, and Director of the Regional Therapies Program in the Cutaneous Oncology Department at Moffitt.

Moffitt Cancer Center is one of the largest melanoma treatment centers in the United States and has been involved in the development of innovative therapies for locoregional melanoma, as well as for distant metastatic disease.

Additional information about this Phase 3 clinical study of DAROMUN is available at www.clinicaltrials.gov using identifier: NCT02938299.