

## **MEDIA STATEMENT**

### **PHILOGEN ANNOUNCES COMMENCEMENT OF PHASE III PIVOTAL TRIAL IN MELANOMA**

Siena, Italy, 21<sup>st</sup> January 2016. [Philogen S.p.A.](#) today announced the launch of a pivotal trial in patients with Stage IIIB/C melanoma, following promising results obtained in a Phase II study with an innovative immunotherapeutic approach.

Stage IIIB/C melanoma patients are at high-risk of progression to the aggressive Stage IV of the disease, which is in most cases fatal. Surgery is the first therapeutic option in Stage IIIB/C patients, and is performed with a curative intent. However, unfortunately, most patients undergo further recurrences of disease and surgery becomes no longer feasible. Therefore the ability to eradicate metastatic lesions, using a biotherapeutic approach which provides a protective anti-cancer immunity, would offer an opportunity to prevent progression and prolong survival.

In a recently published Phase II clinical trial, the Philogen group and collaborating Clinical Centers have demonstrated that the intratumoral injection of a combination of two immunocytokines (L19-IL2 and L19-TNF $\alpha$ ) is able to substantially reduce or eradicate injected melanoma lesions, with durable responses and excellent cosmetic results. In addition, there was evidence of systemic bystander effects on non-injected lesions, indicating the onset of a protective anti-cancer immunity [Danielli et al. (2015)]. These data reinforce the findings of a previous Phase II clinical trial [Weide et al. (2014)] and of extensive preclinical investigations [Schwager et al. (2013); Pretto et al. (2014)].

During the month of December 2015, the Competent Authorities of Italy and of Germany have authorized the conduct of an international multi-center controlled Phase III pivotal clinical trial. The study will feature initially the participation of 15 leading European Dermato-Oncology Clinical Centers. ‘We are pleased to be working with Key Opinion Leaders in the field of cancer immunotherapy, and to be exploring the potential of our immunocytokines to provide benefit to patients’ commented Dr. Duccio Neri, Philogen’s CEO.

### **About Philogen**

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 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 five Phase I/II drugs and also pre-clinical compounds. Philogen is headquartered in Siena, Italy, and has research activities at Philochem in Zürich, Switzerland. Philogen is independently owned and has signed agreements with major pharmaceutical companies. For more information please visit [www.philogen.com](http://www.philogen.com)

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