SOTIO initiates first-in-human clinical trial with IL-15 superagonist SO-C101

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Source: Press Release

SOTIO and Cytune Pharma, members of the PPF Group, announce today the first dosing of cancer patients with SO-C101, a superagonist fusion protein of interleukin IL-15. The phase I/Ib study (SC103) will evaluate the safety and preliminary efficacy of SO-C101 in patients with selected advanced/metastatic solid tumors.

The first patient was treated with SO-C101 at the Institute Gustave Roussy (France). The SC103 clinical trial will also enrol patients in the Vall d'Hebron cancer center (Spain) and, subject to obtaining all the necessary approvals, at the Yale Cancer Center in New Haven, CT and MD Anderson Cancer Center in Houston, TX. Cytune Pharma is responsible for the clinical development of SO-C101, SOTIO is sponsor of the SC103 clinical trial.

Aurélien Marabelle, M.D., Ph.D., coordinating investigator of the phase I/Ib trial said: *"I am very pleased that our medical center has enrolled the first patient in this important clinical trial. We believe that SO-C101 has the potential to make a life-changing difference to many patients with difficult-to-treat forms of cancer. I am looking forward to further advancing this innovative therapy."*

"SO-C101 is a very innovative approach which has been validated for its efficacy and safety in preclinical experiments. Since SO-C101 is an ideal combination partner for checkpoint inhibitors, monoclonal antibodies and other well established therapies, the planning for additional combination trials is already ongoing," said Radek Spisek, M.D., Ph.D., CEO of SOTIO.

"I'm excited that after 12 years of research and development at Cytune Pharma, which was based on previous research from INSERM and the University of Nantes and supported by Bpifrance and Atlanpole Biotherapies, our invention has now entered the clinical development phase. I hope that SO-C101 will become a treatment for cancer patients in the future," adds David Bechard, Ph.D., President and COO of Cytune Pharma.

Description of clinical trial

SC103 (Eudra CT: 2018-004334-15): A multicenter open-label phase 1/1b study to evaluate the safety and preliminary efficacy of SO-C101 as monotherapy and in combination with pembrolizumab in selected patients with advanced/metastatic solid tumors. SOTIO received a positive decision allowing launch of SC103 clinical trial within the EU Voluntary Harmonisation Procedure (VHP) in February 2019.

About SO-C101

SO-C101 (RLI-15) is a human fusion protein of IL-15 and the high-affinity binding domain of IL-15Rα which acts as a specific agonist of the intermediate-affinity IL-2/IL-15Rβγ. It is a novel immunotherapeutic approach with potential applications in a variety of oncology indications. In preclinical experiments, SO-C101 has been shown to stimulate and induce proliferation of immune effector cells, such as cytotoxic T cells and NK cells, without expanding the CD4+ T regulatory cells. Based on the preclinical experiments, SO-C101 is more potent and better tolerated compared to the unmodified IL-15 or IL-2. SO-C101 and other products based on this platform allow for combinations with other immunotherapeutic strategies, including checkpoint inhibitors. SO-C101 is developed by Cytune Pharma (France), an affiliated company of SOTIO.