

Press Release

SOTIO Announces Clinical Collaboration with MSD to evaluate IL-15 Superagonist, SOT101, in Combination with KEYTRUDA® (pembrolizumab) in Patients with Solid Tumors

- **The Phase 2 AURELIO-04 study is expected to enroll up to 300 patients across six different indications**
- **The study will be conducted in the US and selected European countries and will begin in the first half of 2022**

Basel, December 8, 2021

SOTIO Biotech, a clinical stage immuno-oncology company owned by PPF Group, announced today that it has entered into a clinical trial collaboration and supply agreement with MSD, a tradename of Merck & Co., Inc., Kenilworth, NJ., through its subsidiaries, to evaluate the combination of SOT101, SOTIO's IL-15 superagonist, and MSD's KEYTRUDA® (pembrolizumab) in patients with selected advanced/refractory solid tumors in the phase 2 AURELIO-04 study.

“SOT101 in combination with KEYTRUDA has shown promising clinical efficacy across multiple indications in our ongoing phase 1/1b AURELIO-03 study,” said Radek Špišek, Ph.D., Global CEO of SOTIO. “We are excited to collaborate with MSD, a global leader in oncology, to continue studying the combination as part of the AURELIO-04 study for the treatment of certain patients with solid tumors while exploring the full potential of SOT101. We look forward to advancing SOT101 to the benefit of patients globally.”

Under the terms of the agreement, SOTIO will conduct a Phase 2 open-label, multicenter study of SOT101 in combination with KEYTRUDA to evaluate efficacy and safety in patients with selected advanced or refractory solid tumors. The study is expected to treat up to 300 patients with a combination of SOT101 and a standard dose of KEYTRUDA. The study will enroll patients in the U.S. and selected European countries across six different indications, including second line non-small cell lung cancer, first and second line cutaneous squamous cell carcinoma, first line microsatellite instability-high colorectal cancer, second line hepatocellular carcinoma, first line metastatic castration-resistant prostate cancer, and second line ovarian cancer. MSD will supply KEYTRUDA for the study.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp, a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

About SOT101:

SOT101 (SO-C101) is a subcutaneously-administered IL-15 superagonist that is fused to the sushi+ domain of the IL-15 receptor α chain. SOT101 has demonstrated strong preclinical *in vivo* efficacy in various tumor models showing increased long-term survival and tumor regression, as well as a favorable toxicology profile. SOT101 has been shown in pre-clinical models to synergize with checkpoint inhibitors and antibody therapies exerting ADCC.

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About SOTIO Biotech

SOTIO Biotech is shaping the future of cancer immunotherapies by translating compelling science into patient benefit. SOTIO's robust clinical pipeline includes a differentiated superagonist of the attractive immunoncology target IL-15, SOT101, currently being tested in phase II clinical trials. Three programs will enter phase I clinical testing within the next 12 months, including SOT201, and IL-15-based immunocytokine, BOXR1030, a GPC3-targeted CAR-T based on proprietary

technology designed to improve on the efficacy of CAR T therapies in the tumor microenvironment and SOT102, a next generation Claudin18.2-targeted antibody-drug conjugate (ADCs). SOTIO is a member of the PPF Group. For more information, please visit the company's website at www.sotio.com.

SOTIO is a registered trademark of SOTIO Biotech a.s. in selected countries.