**ILTOO Pharma and the MIROCALS Consortium announce the signing of Licence Agreement for the development of low dose interleukin-2 as a potential treatment for Amyotrophic Lateral Sclerosis (ALS)**

Paris, 9 May 2023

ILTOO Pharma SAS of Paris France and the European MIROCALS Consortium announced today the signing of a **Worldwide Exclusive License Agreement** granting ILTOO Pharma the use of data from the H2020 funded MIROCALS project to develop low dose interleukin-2 (IL-$2_{LD}$) as a treatment for **Amyotrophic Lateral Sclerosis (ALS)**.

José Achache, Chairman of ILTOO Pharma, commented on the License saying, "We are grateful to the MIROCALS Consortium and to the Study Sponsor for their dedicated efforts to find an effective treatment for this debilitating disease. This is a significant achievement, and we are proud to be selected to bring it to patients who so need it. The company is well positioned to seek approval for the treatment and has made significant progress already. Future announcements will provide details of our progress. For now, we are focusing on providing the treatment on a compassionate basis for patients who participated in the trial."

Professor David Klatzmann, founder of ILTOO Pharma and Chairman of ILTOO Scientific Advisory Board, who pioneered the field of low dose IL-2 (IL-$2_{LD}$) treatments for autoimmune diseases and conducted clinical trials in Systemic Lupus Erythematosus, Multiple Sclerosis and many other auto-immune and inflammatory diseases commented on the licence, "Drawing on the accumulated knowledge of IL-$2_{LD}$ biology coupled with ILTOO's expertise in drug development will enable us to make rapid progress in our mission to provide an innovative and effective treatment for patients suffering from ALS. This will also accelerate our developments for treatments of other autoimmune diseases."

Mr Nicolas Best, general director of Centre Hospitalier Universitaire de Nîmes, coordinator of the MIROCALS Project and Consortium, and Sponsor of the clinical study, said, "We are delighted with the signing of this licence agreement which potentially opens the way to a therapeutic improvement in the care of people with such a terrible disease, and demonstrates the great value of European academic research. It is an honour for the Consortium's members that the substantial funding provided by the European Commission H2020 and the French Ministry of Health research programmes, supplemented by the Motor Neurone Disease Association and other ALS Charities, has made it possible to produce data of interest to a Pharma company and to accelerate the exploitation of the trial results in line with the ultimate innovation goals of the Horizon 2020 Programme."

"Additionally, we are proud to contribute to the development of a European start-up company, ILTOO Pharma, and to entrust it with the mission of pursuing and achieving the goals which motivated the MIROCALS study and its consortium members."

Dr Gilbert Bensimon, Project Coordinator, said, "We believe our trial results show that IL-$2_{LD}$ treatment has the potential to positively impact the health of people affected by this devastating condition. We welcome this agreement as a critical step toward making this promising therapy accessible for the whole ALS community."

Professor Nigel Leigh, Chief Investigator and co-coordinator, from the University of Sussex, commented further, "Without the altruism and commitment of all the people with ALS who volunteered to join the trial, MIROCALS could not have succeeded. We must now do our best to translate our findings into benefit for all people with ALS, for which collaboration with ILTOO Pharma is essential."

Dr Brian Dickie, Research Director at the UK Motor Neurone Disease (MND) Association said, "ALS is a devastating and ultimately fatal disease, with very limited treatment options presently available. Novel therapeutics are desperately required, and this licence agreement will hopefully provide the springboard for rapid development of low dose IL-2 to address this urgent unmet medical need."

About Amyotrophic Lateral Sclerosis:

Amyotrophic lateral sclerosis (ALS), also known as Charcot's disease or Lou Gehrig's disease, is an adult-onset motor neuron disease and is usually diagnosed between the ages of 40 and 70. It is a life-limiting neurodegenerative disease that affects about 42,000 patients in Europe and approximately 20,000 patients in the US. There is currently no cure for ALS and no effective treatment to stop or reverse the progression of the disease.

About the MIROCALS consortium:

MIROCALS (Modifying Immune Response and Outcomes in ALS) is a European Consortium including research laboratories in the UK (King's College London, Queen Mary University of London, University of Sheffield), Italy (Humanitas Research Hospital), and Sweden (University of Gothenburg), and research support organisations in Ireland (ICON plc), in France (Genéthon), and the UK (WGK Clinical Services Ltd). The Study was coordinated by Dr Gilbert Bensimon of the Centre Hospitalier Universitaire de Nîmes (France). The Principal Investigator of the trial is Professor Nigel Leigh of Brighton and Sussex Medical School, the University of Sussex (UK).

About The MIROCALS trial (NTC03039673):

The randomised, double-blind, placebo-controlled clinical trial involved 17 ALS Clinical research centres across France and the United Kingdom, together randomising 220 patients, treated for 18 months and followed-up for 21 months. Results presented at the MND Association meeting December 6th, 2022, found that IL-$2_{LD}$ significantly improves survival compared to placebo over the follow-up period, with no major safety issues. The MIROCALS project was funded through the European Commission H2020 programme and the Motor Neurone Disease Association, with additional support from the Programme Hospitalier de Recherche Clinique (French Health Ministry), My Name'5 Doddie Foundation, MND Scotland, Association pour la Recherche sur la Sclérose Latérale Amyotrophique, AFM-Telethon and the Alan Davidson Foundation.

Further information on the MIROCALS trial can be found here:
https://clinicaltrials.gov/ct2/show/NCT03039673
https://www.mndassociation.org/research/clinical-trials/mirocals/
https://symposium.mndassociation.org/wp-content/uploads/2022/10/The-MIROCALS-Study-Group.pdf

About ILT-101:

ILT-101 is the lead drug of ILTOO Pharma SAS. It is a ready-to-use, injectable liquid form of IL-$2_{LD}$ available in vials, designed to better fit patient needs. The medication has been formulated to be easy to use and more suitable for long-term treatment, with a unique formulation that enables stability over a period of 36 months. Future plans include making ILT-101 available in a self-injector for patients. The drug has been developed to treat a wide range of diseases including auto-immune and inflammatory diseases and certain central nervous system conditions.

About ILTOO Pharma:

ILTOO Pharma is dedicated to the development of immunotherapies with IL-$2_{LD}$ for the treatment of certain autoimmune, neurological and inflammatory disorders. The company is based near central Paris within a thriving community of Bio Pharma research and commercialisation.

For further information, please visit our website at: http://www.iltoopharma.com/