LobSor Pharmaceuticals and TFS report LECIGon® Achieving Its Primary Endpoint in a Pivotal EU Study for Advanced Parkinson's Disease

- LobSor plans to submit its regulatory application for EU approval in early 2016
- LobSor in process of planning discussions with the U.S. Food and Drug Administration (FDA) to outline US path to commercialization

LobSor Pharmaceuticals, a specialty pharmaceutical company based in Sweden, announced that LECIGon® has achieved its primary endpoint in a late-stage study examining the pharmacokinetics of LECIGon® compared to Abbvie's Duodopa® in the treatment of advanced Parkinson's disease. When comparing the levodopa bioavailability during daytime enteral infusion, LECIGon demonstrated superiority over Duodopa with a 38% increase in bioavailability (p value <0.0001). When analyzed over 24 hours, this translates to a 54% increase in bioavailability over Duodopa.

Under its risk-sharing agreement with LobSor for the development of LECIGon, TFS International is responsible for the regulatory strategy, clinical development planning and execution including the regulatory Marketing Authorization (MA) filing. No equity transaction is involved in the risk-sharing partnership the commercial upside for both parties relies upon a successful regulatory approval of the MA which is expected in the second half of 2016. Discussions with the U.S. Food and Drug Administration (FDA) to outline U.S. commercialization are also planned.

The clinical trial was a single centre, two-period, cross-over, open label, randomized study in 11 patients. All patients received both treatments, Duodopa and LECIGon over two consecutive days. Each treatment consisted of a morning dose, a continuous infusion, extra doses as needed, and flushing of the tube at the end of infusion. Patients were randomized to treatment sequence. The clinical trial was successfully managed by the Clinical Development Organization of TFS.

"This is a logical development of the concept of levodopa infusion, which is highly effective in treating motor and non-motor fluctuations in advanced Parkinson's disease", ***said Associate Professor Dag Nyholm, principal investigator*** *at the neurology department, Uppsala University Hospital, Sweden. "The results are in line with our expectations."*

"The results of the study highlight the benefits of LECIGon for advanced PD patients" said ***Professor Angelo Antonini*** *director of the Parkinson Unit at the Hospital San Camillo in Venice. "Achieving these positive clinical results with significantly lower levodopa dose is very important because it may reduce adverse events and improve treatment accessibility. Furthermore, the smaller pump system will likely be considered as a great leap forward by the patients."*

"We are extremely pleased with the positive results seen in this trial," said Patricia A. Mosher, EVP, Global Clinical Development at TFS. "Our team worked very effectively in the execution of this trial to support aggressive timelines that were defined in June of 2014 when we entered into this agreement".

We are pleased with the results of the EU registration study for LECIGon", said Roger Bolsoy, President of LobSor Pharmaceutical. "Our strategy has initially focused on Europe and we anticipate filing for approval in early 2016. We are also in the midst of preparing for a pre-IND meeting with the FDA to discuss the pathway to commercialization in the US. If approved, LECIGon will serve as an optimal treatment option for advanced PD patients."

Information about LECIGon

LECIGon is a proprietary gel formulation of levodopa, carbidopa, and entacapone for continuous intestinal administration through a proprietary small, lightweight ambulatory pump system. The intention is to offer a treatment system with an improved safety profile, maintained clinical efficacy, enhanced user convenience, and thus improved Quality of Life compared to existing advanced treatment options. Adding entacapone to levodopa/carbidopa results in a superior bioavailability of levodopa and is expected to reduce the daily levodopa dose needed to maintain a clinical effect. A reduction in daily levodopa exposure is expected to reduce adverse levodopa-related side effects, including exposure to higher levels of metabolic byproducts such as homocysteine and 3-OMD. Continuous intestinal delivery,

tailored for the individual patient, has been shown to secure a smooth levodopa plasma level, thereby offering a true continuous dopaminergic stimulation and resulting in a predictable and stable clinical effect.

Information about LobSor Pharmaceuticals

LobSor Pharmaceuticals is privately owned via LobSor Holding AB and based in Uppsala, Sweden. The founders and main owners of the company, Roger Bolsöy and Ulf Rosén have extensive experience in the development, sales, and marketing of pharmaceutical products and medical devices – with a particular focus on advanced Parkinson's disease. The Company's first product – LECIGon has been developed in close collaboration with Recipharm, TFS International and internationally renowned clinical experts – together with active support from investors.

Information about TFS

TFS International is the leading global mid-size clinical Contract Research Organization (CRO). Founded in 1996 in Sweden, TFS currently operates in over 20 countries throughout Europe, USA, Canada and Japan and employs more than 700 professionals. TFS core therapeutic areas of expertise are Oncology, Immunology, Dermatology, Ophthalmology, CNS, Cardiology and Endocrinology. Through two business areas, TFS Develop™ and TFS People™, TFS provides services worldwide as end-to-end solutions or tactical functional services. Detailed information about TFS, its business offerings, global locations and recent press releases can be obtained through www.tfscro.com

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