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## Press Release

Uppsala, September 17, 2020

### **Lobsor Pharmaceuticals receive approval for Lecigon in Germany, the Netherlands, Belgium, Austria, Slovenia and Romania**

Lobsor Pharmaceuticals AB today announced that Lecigon, a treatment system for Parkinson's disease has been approved (the MPA, Swedish Medical Products Agency has confirmed End of Procedure) according to the European Mutual Recognition Procedure (MRP) in Germany, the Netherlands, Belgium, Austria, Slovenia and Romania. This follows the marketing authorization for Lecigon granted in Sweden in 2018 as well as Denmark, Finland and Norway in 2019. Immediately after the MRP Approval, the procedure enters a national phase for approval of labels, package inserts etc. in the local languages. The national phase is expected to be finalized at the end of October 2020 when the national market authorizations can be granted, and subsequent commercialization initiated.

- The approval from the MPA and the end of the European Mutual Recognition Procedure for Germany, the Netherlands, Belgium, Austria, Slovenia and Romania is yet another important milestone achievement by the Lobsor team. It brings us one step closer to achieving our mission to not only develop new technologies for treating patients suffering from Parkinson's but also to ensure that those technologies reach the market and can improve their daily lives said Ulf Rosén, Co-founder and CEO of Lobsor Pharmaceuticals.

Lobsor Pharmaceuticals is a privately held company based in Uppsala, Sweden founded in late 2013. It is a fully owned subsidiary of Lobsor Holding AB. The founders Ulf Rosén and Roger Bolsöy have significant experience in treating Parkinson's disease in advanced stages, especially continuous infusion of levodopa into the small intestine via a pump. They have developed the Lecigon treatment system by drawing on that experience and collaborating closely with leading neurologists and patient

organizations. The aim of Lecigon is to improve the daily lives of individuals who are affected by progressive Parkinson's disease and suitable for an invasive treatment.

Marketing authorization for Lecigon was granted in Sweden in 2018, and in Denmark, Finland and Norway in 2019. In 2018, the founders established a US company, Intrance Medical Systems Inc. which is responsible for obtaining market authorization in the US and Canada. The company is already in talks with the US medical products agency (FDA) and expect to file the IND (Investigational New Drug application) in Q4 2020.

### **About Parkinson's disease**

Parkinson's disease (PD) is the second most common neurodegenerative disorder after Alzheimer's disease, and the incidence is expected to rise with an aging population.

PD is age-related and affects nearly 1% of the population over 60 years and 5% over 85 years, with a substantial health, social, and economic impact. PD is a progressive disorder in which dopaminergic neurons are degenerated. Dopamine deficiency at (striatal) receptor sites presents as both motor and non-motor disability such as bradykinesia (slow movement), tremor, rigidity (stiffness), postural instability, depression, and sleep disturbance. The symptoms vary between patients and the number of symptoms and the severity tend to increase over time, creating a more complex clinical picture.

Parkinson's disease, particularly in its advanced stage is a devastating disease with symptoms including uncontrollable shaking or tremor, lack of coordination and speaking difficulties. An estimated seven to ten million people worldwide are living with Parkinson's disease, and for most patients the disease will eventually reach the advanced stage. Additionally, erratic gastric is an important cause of patients becoming refractory to oral treatment. Techniques are therefore used to bypass the stomach by introducing a small tube via the abdomen wall for pharmaceutical infusion into the duodenum. As the disease progresses, patients eventually reach the stage of Advanced Parkinson's disease. It is estimated that about 10% of individuals with PD are in the advanced stage, of whom only 10–30% receive adequate treatment.

### **About Lecigon®**

Lecigon is a new therapeutic system for symptomatic treatment of Advanced Parkinson's Disease (APD). Lecigon is a proprietary pharmaceutical gel formulation containing a combination of

levodopa/carbidopa and entacapone in a 47 ml pre-filled container for continuous infusion into the small intestine through a newly developed lightweight wearable pump that weighs 134 grams.

Lecigon is an evolution of Stalevo, a widely used oral therapeutic in earlier stages of PD. Lecigon is formulated and designed for individuals with Advanced Parkinson's disease.

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