

Kålsängsgränd 10 D
753 19 Uppsala
Sweden

www.lobsor.com
Corp. id. No.: 556930-4768
VAT no: SE556930476801

Press release

The Swedish Medical Products Agency approves Lecigon®, a new treatment system for patients with Advanced Parkinson's Disease

Uppsala, October 8, 2018. Lobsor Pharmaceuticals AB, a privately held Swedish company based in Uppsala today announced that Lecigon®, a new therapeutic system for symptomatic treatment of Advanced Parkinson's Disease (APD) has been granted marketing authorization by the Swedish Medical Products Agency (MPA). Lecigon® is a pharmaceutical gel formulation containing a combination of levodopa/carbidopa and entacapone for continuous infusion into the small intestine through a newly developed lightweight pump. The combination of lower dosage and lighter pump is designed to significantly improve patient convenience and quality of life. US market entry is under discussion and meetings are being held with the FDA. The current worldwide market for intestinal infusion based on levodopa exceeds USD 400 million in sales over the past 12 months, with an annual growth of > 30%.

Ulf Rosén, Founder of Lobsor comments:

“The current treatment, which was first commercially introduced in 2004, serves patients well. However, many are struggling handling the current pump due to its size, weight and cumbersome operation. Our team has in-depth previous experience of developing Parkinson's disease treatments based on continuous infusion of pharmaceuticals into the small intestine via a pump and we have devoted a great deal of time and effort to overcome all these three hurdles in Lecigon®. In addition, the new patented pharmaceutical preparation increases the bioavailability of levodopa thereby reducing the overall dose and volume of levodopa making the system both smaller and lighter, with maintained clinical efficacy.”

Dag Nyholm, associate professor and Parkinson's disease specialist at Uppsala University Hospital and one of the investigators in the clinical trial with the Lecigon® treatment system, welcomes the new, improved product:

“The most important improvements include the lightweight pump with the possibility to change dose in an easy and convenient way. In combination with a longer shelf life, this also allows for 24 hours treatment for patients who are in need of around-the-clock infusion. Additionally, the new treatment offers a lower levodopa dose when compared to the current treatment system, which is of particular importance for patients requiring high doses. With the new gel formulation, the half-life of levodopa is prolonged, giving the patient important extra minutes off-treatment when for example taking a

shower. Thus, the improved system may benefit the patients in several ways, all adding up to improved quality of life.”

A collaboration agreement has been signed with NordicInfu Care for support during development and for marketing Lecigon® in the Nordic countries. Lobsor is currently exploring various future options for further development of the business.

For further information, please contact:

Ulf Rosén, Founder and chairman of the board of Lobsor Holding AB

Telephone: +46 70 686 29 16

Email: ulf.rosen@lobsor.com

Web: <http://www.lobsor.com/>

About Parkinson's Disease

Parkinson's disease (PD) is the second most common neurodegenerative disorder after Alzheimer's disease. PD is age-related and affects nearly 1% of the population over 60 years and 5% over 85 years, with high 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. No less than an estimated seven to ten million people worldwide are living with Parkinson's disease and for most patients their disease will eventually reach the advanced stage. In addition, erratic gastric functioning is an important part of making patients refractive to oral treatment and techniques are used to bypass the stomach by introducing a small tube via the abdomen wall for pharmaceutical infusion into the duodenum. With disease progression patients eventually reaches the stage of Advanced Parkinson's Disease. It is estimated that about 10% of individuals with PD are in advanced stage, of whom only 10 – 30% receive an adequate treatment. The advanced therapies are expected to continue to grow for many years.

With advancing disease, it becomes increasingly difficult to counteract PD symptoms and one of three options for advanced PD come into play in which the goal is to provide continuous or continuous-like dopaminergic stimulation. These are Deep brain stimulation (DBS), Continuous subcutaneous apomorphine and Levodopa-carbidopa intestinal gel (Duodopa/Duopa in the US). Lecigon offers a new alternative with particularly added convenience so that these patients can live their lives closer to the fullest.

About Lobsor

Lobsor Pharmaceuticals is a privately held company based in Uppsala, Sweden founded late 2013 by Ulf Rosén. In 2014, Roger Bolsøy joined as Co-founder to run the development project. It is a fully owned subsidiary to Lobsor Holding AB. The Lobsor team has substantial previous experience from the treatment of Parkinson's disease in advanced stages especially continuous infusion of levodopa into the small intestine via a pump. Both founders had leading executive roles in NeoPharma during the development and commercialization of Duodopa. Based on this experience, and close liaison with leading neurologists and patient organizations describing the medical needs, the Lecigon treatment system has been developed with the aim of increasing quality of life for individuals affected by progressive Parkinson's disease and suitable for an invasive treatment.

The company have chosen to work with a small core team and use specialized consultants to support the development process, both regarding the pump and the new, patented, pharmaceutical formulation, and maintain structural and financial flexibility. These include TFS International, Recipharm, Brann and the law firm Lindahl. Lobsor's near-term focus is to obtain market authorization in the Nordic countries and key markets in Europe. A newly formed US based company, Intrace Medical Systems Inc. is responsible for commercialization in the US and Canada. Several interactions have already been made with the FDA. Lobsor has signed a collaboration agreement with Nordic InfuCare for market insights in the development phase, in addition to sales, marketing and distribution in the Nordic market. In addition, Lobsor is now exploring various commercial routes forward to ensure that the treatment will be made available for patients in the European market and the rest of the world.

About Lecigon

The new patented treatment is a pharmaceutical gel formulation containing a combination of levodopa/carbidopa and entacapone in a 50 ml pre-filled container for infusion continuously into the small intestine. The pharmaceutical formulation decreases the overall levodopa dose, but with maintained clinical efficacy. The treatment system includes a newly developed wearable pump that weighs only 134 grams. The highly accurate and small pump can be conveniently and discreetly carried under the clothing, with the lightweight pump, neck- and shoulder pain can likely be avoided, an intuitive and user-friendly, illuminated screen on the pump facilitates switching between preset doses, thus potentially providing a feeling of security and trust in daylight and if it is dark.

Lecigon has an approved shelf-life of 24 hours. Thus, patients can prepare the system in the evening and store it beside the bed before going to sleep and start the treatment in the morning while they are in bed, thus avoiding the need to get it from the fridge when they may be in a rigid condition with increased risk of falling. With the 24-hour shelf-life, it is also possible to continue to use a cartridge the next day, something particularly useful for

high dose patients, thus avoiding unnecessary waist. The lower levodopa dose required is due to increased bioavailability of levodopa which prolongs the half-life of levodopa. As a consequence, the time before symptoms occur after the pump is switched off is probably prolonged and will give the patient more time off-treatment when e.g. taking a shower.

About NordicInfu Care

Lecigon will be marketed by NordicInfu Care in the Nordic market and Sweden is the first market for launch. NordicInfu Care with about 80 employees was founded in Stockholm Sweden 2004 and is currently serving > 50,000 patients in the Nordic countries. NordicInfu Care belongs to Air Liquide Healthcare, a company serving 15,000 clinics and hospitals as well as 1.5 million patients with home care.