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Press Release

March 20, 2019

Lobsor granted US patent for new levodopa replacement formulation

Lobsor Pharmaceuticals AB, a privately held Swedish company today announced that it has been granted the US patent (US10,071,069) covering a pharmaceutical composition for the treatment of neurodegenerative disorders such as Parkinson's disease. Lobsor has earlier received market authorization by the Swedish Medical Products Agency (MPA) for their lead product, Lecigon®, a new therapeutic system for symptomatic treatment of Advanced Parkinson's disease (APD). Lecigon comprises the kind of pharmaceutical suspension formulation described in the new patent, containing a combination of levodopa/carbidopa and entacapone for continuous infusion into the small intestine through a newly developed lightweight pump. The patent award reinforces the path for introducing a similar treatment in the US through the company's Partner Intrance Medical Systems Inc.
Levodopa (dopamine replacement agent) in combination with carbidopa has been the primary choice of active substance for continuous treatment of advanced Parkinson's. However, such combination exposes patients to high levodopa load, associated with several long-term side effects. To overcome among others this problem, Lobsor has developed a novel combination of three active substances already in clinical use – a dopamine replacement agent, a DD inhibitor (DD=dopamine decarboxylate) and a COMT inhibitor (COMT=catechol-O-methyltransferas). – which is now covered by the new patent.

The patent also includes a method of preparing the suspension and a method of treating a patient using the suspension. The patent is not limited to any amounts or ratios of the three components, which allows Lobsor to vary and tailor the concentration depending on regulatory demands, patient groups and cost etc

Roger Bolsöy, CEO of Lobsor comments: “We are delighted to receive this new patent to further protect our treatment system. With the new formulation and lightweight delivery pump, we believe Lecigon will significantly improve convenience and quality of life for Parkinson’s patients. Improving bioavailability and achieving a similar clinical outcome with significantly lower levodopa doses means we can also report significant reductions in 3-OMD, a metabolite in a metabolic complex associated with long term side effects of levodopa”.
The US patent expires in September 2035 and a corresponding patent is also granted in Sweden. Lobsor have co-pending applications for the same invention in Europe, Australia, Canada, China and Japan.

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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. 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. 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.

With disease progression patients eventually reach 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 Bolsöy 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, Intrance 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 Intrance Medical Systems Inc.

Intrance Medical is a privately held company based in New York City and founded in January 2018. The Intrance 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 portable pump. The Intrance team had leading roles during the development and regulatory approvals of Duopa both in the US and Japan. Based on this experience, and close liaison with leading neurologists and patient organizations, the ambition is to use the fastest regulatory pathway possible to obtain NDA approval and commence commercialization of Lecigon in the US. Similar to Lobsor, the company have chosen to work with a small core team and use specialized consultants to support the development process.

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 and with the intuitive and user-friendly, illuminated screen on the pump facilitating switching between preset doses, a feeling of security and trust in daylight and if it is dark can potentially be provided.

Lecigon has an approved shelf-life of 24 hours in room temperature. 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.

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