

Nanexa receives approval for NEX-22 clinical study

Nanexa AB today announces that the European Medicines Agency has approved the company's clinical trial application for the Phase I study with NEX-22. NEX-22 is a long-acting depot formulation of the GLP-1 analogue liraglutide with Nanexa's patented PharmaShell® system. The goal is to create a GLP-1 product that can be administered once a month in the treatment of Type 2 diabetes.

The study will be performed in collaboration with the contract research organisation Profil in Germany, which is highly specialized in early clinical studies in diabetes and obesity. The study is divided into several consecutive dose groups where single doses of NEX-22 will be administered to patients with Type 2 diabetes to study pharmacokinetics, safety and tolerability.

"We are thrilled about being involved in this important trial investigating a prolonged release formulation of liraglutide using Nanexa's impressive PharmaShell® technology. We will do our outmost to justify the trust placed into us and look very much forward to starting the clinical trial", says Dr. Tim Heise, Lead Scientist Co-Founder of Profil.

Liraglutide and other GLP-1 analogues have rapidly become important in the treatment of Type 2 diabetes and obesity. The global market for this type of products is very large and is growing with increasing prevalence of both Type 2 diabetes and obesity. Sales of GLP-1 compounds show strong growth and GLP-1 and GLP-1/GIP drugs are expected to reach sales of over USD 70 billion by 2029 for Type 2 diabetes (1).

"I am of course very pleased that we have now got an approval to start the study with NEX-22, a product that we believe has very high potential to reach significant sales levels. Patients are asking for products with less frequent dosing, and we see that also the big pharmaceutical companies express the same desire. NEX-22 replaces daily injections of Victoza with just one NEX-22 injection per month. The study and the first clinical results in this project will be an important milestone for us", says David Westberg, CEO of Nanexa.

(1) Global Data Type 2 Diabetes Forecast Dec 2022

For additional information, please contact:

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The company's Certified Adviser is Carnegie Investment Bank AB (publ).

About Nanexa AB (publ)

Nanexa is a pharmaceutical company developing injectable drug products based on the proprietary and innovative drug delivery system PharmaShell® – the high drug load delivery system enabling the next generation long-acting injectables through atomic layer precision. Nanexa develops its own products and also has collaboration agreements with several pharma companies, among others Novo Nordisk and AstraZeneca.

Nanexa's share is listed on Nasdaq First North Growth Market in Stockholm (NANEXA).

Attachments

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