Press Release
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Nanexa signs contract with leading international diabetes CRO for Phase I study with NEX-22

Nanexa AB today announced that the company is engaging the contract research organization (CRO) Profil, in Neuss, Germany, ahead of the upcoming start of a phase I study with NEX-22, a monthly depot of liraglutide for the treatment of type 2 diabetes and ultimately obesity. Profil is highly specialized in early clinical studies in diabetes and obesity, and has an excellent global reputation for conducting clinical research in these two indications.

Profil is a full-scale CRO specializing in early clinical research and translational research in diabetes and obesity. Since its inception in 1999, the company has been engaged in numerous clinical research studies with some of the world's largest pharmaceutical companies. For its research in these indications, the company has up to 65 beds at its clinic and a team of more than 330 employees, over 25 of whom are physicians.

"We are thrilled to be involved in the development of a once-monthly formulation of liraglutide using Nanexa's advanced drug delivery system PharmaShell®. A GLP-1 analog that only needs to be injected once a month has the potential not only to further facilitate diabetes therapy and enhance patient compliance, but may improve tolerability and efficacy. In close collaboration with the experienced management team and the outstanding expert advisors from Nanexa, we set up a lean development plan to be able to demonstrate proof-of-concept already in early stages of development", says Dr. Tim Heise, Lead Scientist and Co-Founder of Profil.

"Germany is by far one of the largest pharmaceutical markets in Europe and in the world, and is the country in Europe that, with its pricing system, allows sales from day one when a new drug is approved in the EU. The fact that we are already placing our first clinical research study with NEX-22 in Germany, with a CRO that has such a good global reputation in these two metabolic diseases, ensures high quality data with efficient execution for a possible future license partner within the framework of NEX-22", says David Westberg, CEO of Nanexa.

The NEX-22 project is now in the preclinical phase and Nanexa announced earlier this year that a first animal study showed a release of liraglutide over 28 days. Further preclinical studies are now underway, which preliminarily confirm these results.

"The NEX-22 project is very exciting and undoubtedly fills a great medical need, to make it easier for patients to avoid frequent injections of their drug. A depot preparation over a month is in many ways ideal for patients with diabetes or obesity and it also simplifies things for healthcare providers and pharmacies. After all my years in the pharmaceutical industry, I have also realized the importance of establishing good knowledge of a drug's advantages and disadvantages in the research clinics in the countries where it is first launched and begins to be used on a larger scale.", says Bengt Gustavsson, Director of Clinical Research and Medical Affairs at Nanexa.

The phase I study of NEX-22 expected to be ready to start around the end of 2023.

For additional information, please contact:

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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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