All Primary and Secondary endpoints met in Nanexa's Phase I study of the one-month GLP-1 depot NEX-22

Nanexa AB today announce positive results in the company's Phase I study for NEX-22, long acting GLP-1, in type 2 diabetes. The study evaluates a once-monthly depot formulation of the GLP-1 analog liraglutide with Nanexa's patented PharmaShell® system.

The study met all primary and secondary endpoints.

- The pharmacokinetic profile supports a one-month depot of liraglutide, with dose linearity for both Cmax, AUC and depot length.
- No adverse events reported, including no incidences of nausea or vomiting
- No or minimal local reactions was observed

The study was performed at Profil, a world leading diabetes CRO, in Germany and was conducted in type-2 diabetes patients naive to GLP-1 treatment. It included three patients in each of three consecutive cohorts with escalating doses, aiming to assess the pharmacokinetic profile, safety, and tolerability of different dose levels. The first cohort was dosed in June 2024 and the last patient last visit was November 5. The NEX-22 depot formulation was administered as an injection under the skin (subcutaneously).

- We are very pleased with these results. As far as we know, this is the first once-monthly GLP-1 product that has been proven in a clinical setting in patients with diabetes. A one month depot has the clear potential to increase adherence to treatment and increase number of patients staying on treatment for longer time, which is a problem for current treatment options. If we manage to reduce some of the more serious side effects of GLP-1 products like nausea and vomiting it would also largely benefit the patients says David Westberg, CEO of Nanexa.

- These results show that we can make a once monthly product with liraglutide that itself has a great potential. It also opens a broad range of opportunities formulating other GLP-1, GLP-1-GIP or other combination products within the field of type-2 diabetes and obesity treatment. This is a very interesting potential for us going forward says Dr. Göran Ando, Chairman of the Board at Nanexa.

- With these results at hand, we have a green light to continue the NEX-22 project towards commercialization. Our immediate next step will be to initiate active marketing of the project to seek licensing partners to the project already at this stage says Otto Skolling, Director of Business Development at Nanexa.

- Next step in the product development will be to prepare for and execute a Phase Ib/II study with a direct PK comparison to Victoza starting next year. The aim of such a study will be to bridge NEX-22 to Victoza opening for a straight forward 505 (b)(2) regulatory pathway in the US continues David Westberg, CEO of Nanexa

Glucagon-like peptide-1 (GLP-1) receptor agonists are a class of drugs used for the treatment of type 2 diabetes and obesity. Liraglutide is a GLP-1 agonist developed by Novo Nordisk and included in currently marketed products Victoza and Saxenda, which both require daily injections.

A live commentary with Dr. Göran Ando Chairman of the Board, David Westberg CEO, Otto Skolling Director Business Development will take place on November 25 at 14:00 pm via Infront Direkt Studios and viewers will have the opportunity to ask questions via chat.

The comment will be available here.

The comment will also be published on Nanexa's website afterwards.

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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).

This information is information that Nanexa is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-11-22 17:45 CET.

Attachments

All Primary and Secondary endpoints met in Nanexa's Phase I study of the one-month GLP-1 depot NEX-22