Equity Research | Nanexa AB: Phase I results position NEX-22 for licensing opportunities and a head start in long-acting GLP-1

The positive results in Nanexa's Phase I study for NEX-22, a once-monthly depot formulation of the GLP-1 analog liraglutide for type 2 diabetes, have significantly improved Nanexa's chances of securing a much-needed license deal. Now, plan A is to find a licensee for the Chinese market to fund further development, with hopes of a US/EU license deal after the completion of Phase Ib/II. With our updated model estimate of 45% likelihood of success in the next phase, 70% in Phase III and 95% approval, we now find support for an rNPV for NEX-22 alone of SEK 730m or SEK 5.4 per share (up from SEK 205m/SEK 1.5 per share). On the other hand, we' ve lowered the probability of a license deal with Novo Nordisk from 30% to 20% following their $285m license agreement with Ascendis for a once-monthly GLP-1 drug. All in all, this means that we now find support for an rNPV of SEK 6.4-11.3 (2.6-9.9) per share, noting that the wide valuation range has narrowed to center around NEX-22. This however, does not factor in another rights issue, which is the likely scenario if a license deal does not materialize within the next 6 months.

The first clinical demonstration of a once-monthly GLP-1
The Phase I study of NEX-22, a once-monthly depot formulation of liraglutide (a GLP-1 analog) conducted in collaboration with Profil, a leading diabetes CRO, met all primary and secondary endpoints, demonstrating dose linearity, a one-month pharmacokinetic profile, and no significant adverse events, including the absence of nausea or vomiting. Minimal or no local reactions were observed. This is especially encouraging considering that the dose administered was 17x the normal daily dose. Liraglutide, developed by Novo Nordisk, is currently marketed as Victoza and Saxenda, both requiring daily injections, unlike NEX-22's once-monthly.

The trial involved three dose-escalation cohorts of type 2 diabetes patients, with the first dose administered in June 2024 and the study concluding in November 2024. Subcutaneous administration proved effective, and the results indicate significant potential for increasing patient adherence and reducing treatment discontinuation, common issues with existing daily GLP-1 products like Victoza and Saxenda. The results mark the first clinical demonstration of a once-monthly GLP-1 product for diabetes patients. With these results, Nanexa plans to actively seek licensing partners for NEX-22 and advance to Phase Ib/II studies next year. These studies aim to directly compare NEX-22 to Victoza and explore a 505 (b)(2) regulatory pathway in the US.

NEX-22 an attractive proposal for new entrants into GLP-1
With the positive Phase I results, we now expect smoot sailing towards initiating Phase Ib/II in Q3' 25 and Pre-IND with FDA by the end of 2025. After Phase III with some 400 patients, an application for NEX-22 could realistically be submitted in 2028 and with a product on the market by 2029,

some three years ahead of any competing long-acting Semaglutide drug. This should be a highly attractive proposal for a potential licensee of NEX-22. Furthermore, it is worth keeping in mind that the 505b-path to approval (for new or modified versions of previously approved drugs) can roughly be compared to Phase III for a New Chemical Entity.

Read the full report here: http://emergers.se/nanexa-z24

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Attachments

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