Nanexa obtains pharmacokinetic data from the NEX-20 Phase 1 study confirming controlled release of lenalidomide

Nanexa AB today announced that pharmacokinetic data from the Phase 1 study NEX-20-01 confirmed a release profile of lenalidomide in different doses up to 21 days.

All pharmacokinetic samples are now analyzed from nine healthy volunteers who have been administered either one or two subcutaneous single injections of the studied formulation NEX-20A, with 15, 25, or 35 mg of lenalidomide up to a total dose of maximum 50 mg. The human pharmacokinetic data in the study corresponded very well with the predicted exposure based on preclinical studies, showing a plasma curve of 21 days controlled by the release from PharmaShell®. A low initial release of the total dose was observed in the first day, which is important to maintain plasma levels over the entire treatment period. The total exposure in plasma (AUC) was confirmed to increase with increasing administered dose.

The final compilation of safety and tolerability data will be done after the last follow-up visits for the last dose group in October. Special focus for studies with Long Acting Injectables is to study local tolerability at the injection site. The local adverse events reported to date with NEX-20 have been limited and transient injection site reactions. No unexpected systemic or severe side effects have been reported during the study so far.

"This is an important achievement for Nanexa, to once again demonstrate that we can predict the release profile of PharmaShell® in humans based on preclinical data. We are now continuing to optimize the formulation and are ready to plan for the next clinical study of NEX-20 in patients. In that study, where we plan to increase the dose, we want to ensure that we will continue to minimize local reactions, and we see good results from preclinical studies on how this can be done. The ability to control the release profile while minimizing side effects at the injection site is a great opportunity for Nanexa and for the NEX-20 project", said David Westberg, CEO of Nanexa.

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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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