Nanexa completes clinical phase I study with NEX-20

Nanexa AB today announces that the phase I study NEX-20-01 has been completed with the last follow-up visits for the last of the three dose levels studied. Nanexa has previously communicated positive results from the pharmacokinetic evaluation and has now also completed the collection of safety and tolerability data that also supports the further development of the project.

NEX-20-01 did not reveal any unexpected findings that question the safety of lenalidomide as a depot formulation with PharmaShell®. However, local reactions were observed with redness and /or swelling corresponding to the area of injection with the given formulation of NEX-20. The reactions ranged from mild at the lower dose levels to moderate at higher doses. All reactions subsided during the study period.

The next step in the clinical program for NEX-20 is to proceed with dose escalation to therapeutic levels in patients. The formulation studied in NEX-20-01 shows a controlled release pharmacokinetic profile close to that required for once-monthly dosing.

In parallel with the completed clinical study, a preclinical study has been conducted in minipigs with a new formulation of NEX-20 with significantly less swelling at the injection site compared to the formulation used in NEX-20-01. This formulation will be further developed and tested preclinically to minimize local reactions in the next clinical study.

"We are breaking new ground with NEX-20," said David Westberg, CEO of Nanexa. "This is the first time lenalidomide has been administered as a subcutaneous injection in humans, to our knowledge. We are pleased that we have a PharmaShell formulation of NEX-20 that provides a controlled release and that with the PharmaShell system we are well positioned to minimize tissue impact at the injection site, which is a known challenge for subcutaneously administered depot drugs."

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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