Nanexa takes next step in development of NEX-18

Nanexa AB (publ) today announces that the company's preclinical investigation indicates the cause and a potential solution to the moderate skin reactions that arose in the clinical study with NEX-18. With these results, Nanexa is expanding its preclinical program to optimize the formulation of NEX-18. The project is expected to re-enter clinical phase next year.

The inclusion of patients in the Phase 1 clinical trial of NEX-18, a long-acting injectable azacitidine using the PharmaShell® technology, was paused in September 2021 due to moderate skin reactions at the injection site, and since October 2021, additional preclinical studies have been underway to clarify the cause. These complementary preclinical studies have so far shown that PharmaShell itself is not the cause of the skin reactions. The results also indicate a potential solution to the problem. Therefore, the company is now focusing on a reformulation of NEX-18 with the goal of taking the project forward with an optimized product. The reformulation will be studied further preclinically during 2022. Given continued positive results, the clinical phase of the project will then be resumed.

"We are pleased to confirm that the preclinical studies show that it is not the PharmaShell system that has caused the skin reactions. We also believe we have a good solution for how the formulation of NEX-18 can be optimized. A solution that we could also benefit from in other projects. Overall, we have learned very much, at an early stage, which is of great value for the further development of the project. At the same time, we are focusing on moving forward with the NEX-20 project, a depot formulation of lenalidomide for the treatment of multiple myeloma, ensuring that it runs as planned with the start of a first clinical study during the fourth quarter of this year," said David Westberg, CEO for Nanexa.

As previously communicated, the clinical study preliminarily showed that PharmaShell works as expected in creating a beneficial pharmacokinetic (PK) profile.

"It is very gratifying that we obtained convincing PK results in the patients included in the clinical study before it was stopped. The release of azacitidine over time was very similar between patients and was consistent with the release profile we have received in preclinical studies," said David Westberg.

For additional information, please contact:

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About Nanexa AB (publ)

Nanexa AB is a nanotechnology drug delivery company focusing on the development of PharmaShell®, a new and groundbreaking drug delivery system with great potential for a number of medical substance types and indications. Within the framework of PharmaShell®, Nanexa devlops its own products and has collaboration agreements with several pharma companies, among others 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 2022-02-10 14:06 CET.

Attachments

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