

Nanexa receives clinical trial approval for NEX-18

Nanexa AB (publ) today announced that the company has received permission to start the clinical trial for the drug candidate NEX-18 by the Swedish Medical Products Agency, Läkemedelsverket.

"This is a major and important milestone for Nanexa as it is the first clinical study with a drug based on PharmaShell®. The approval means that we can now start the NEX-18 study according to the set schedule. It is also a validation of quality that shows that we have done the right things on our way to becoming a real pharmaceutical company," said David Westberg, CEO of Nanexa.

The NEX-18 product is being developed to improve the treatment of MDS (Myelodysplastic Syndrome), a form of leukemia that mainly affects the elderly. This is done by utilizing the unique properties of PharmaShell® to create a depot formulation with controlled release. In today's treatment, injections are given in hospitals seven days in a row every month and the goal of the NEX-18 project is to simplify the treatment by only having to give one injection. In addition to greatly simplifying for patients, the company expects that NEX-18 will also reduce the costs associated with current treatment. The study, which is a so-called PK study (phase I), will be conducted at Karolinska University Hospital in Stockholm and Akademiska Sjukhuset in Uppsala.

"With the approval we will now intensify the preparations at the clinics so recruitment of patients can start as soon as possible. The inclusion of elderly, fragile leukemia patients may be more difficult than normal during the pandemic, but with two clinics involved, we minimize that risk. We expect to complete the study in the third quarter of next year," said David Westberg.

For additional information, please contact:

David Westberg – CEO, Nanexa AB (publ)

Phone: +46 70 942 83 03

Email: david.westberg@nanexa.se

www.nanexa.com

Erik Penser Bank is the company's Certified Adviser and can be reached on +46 8 463 83 00, email: certifiedadviser@penser.se

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 in a number of medical indications. Within the framework of PharmaShell®, Nanexa has partnership agreements with among others, AstraZeneca.

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Attachments

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