

Nanexa receives extended GMP-certificate for the new pilot plant

Nanexa AB (publ) today announced that the company's new pilot plant in Uppsala has received certification from the Swedish Medical Products Agency for production of clinical trial material.

Nanexa has since before a GMP-certificate for small scale production and release of clinical trial material. The new larger pilot plant is designed for larger scale and more efficient production, and also to handle production of toxic as well as biological drug products with the Atomic Layer Deposition technology.

In June 2022, the Swedish Medical Products Agency made an inspection of Nanexa's new pilot plant and updated quality system in order to issue a certificate for production and release of clinical trial material. The inspection was made without any major observations and, following the company's answers and actions in response to outstanding questions, the final approval and certificate was today received.

"It is very gratifying that our hard work with completion and quality assurance of the pilot plant, and continued GMP compliance, has been carried out successfully and following the time plan. With this certification, we can now produce material for clinical studies, the first one being the phase I study in our own NEX-20 project which is planned to start during the fourth quarter of this year", said David Westberg, CEO of Nanexa. "The fact that we now have GMP-certificate for the new pilot plant and a complete quality management system is a further step to bring additional projects into clinical development and very important in discussions with potential partners regarding future projects".

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About Nanexa AB (publ)

Nanexa is a pharmaceutical company developing parenteral 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 AstraZeneca.

Nanexa's share is listed on Nasdaq First North Growth Market in Stockholm (NANEXA).

Attachments

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