

Karolinska Development Portfolio Company Launches GMP Facility for Particulate Manufacturing

STOCKHOLM, SWEDEN – August 24, 2009. Karolinska Development (publ), managing one of the largest portfolios of life science research companies in Europe, announced that XSpray Microparticles AB has launched a GMP production facility in Malmö, Sweden. In addition to offering particle development and characterization services, XSpray can now provide customers with high quality drug particles and powders for use in their clinical studies.

Conny Bogentoft, CEO of Karolinska Development, said, “We are extremely pleased with the development of this technology. The ability to produce GMP material is an important step both for XSpray and for Karolinska Development. It will enable this remarkable solution for pharmaceutical particle production to benefit other companies within our portfolio as well as external customers. Currently we have twelve companies with ongoing clinical trials, seven in Phase II and five in Phase I, and the need for high quality GMP material is increasing as our portfolio matures.”

XSpray’s RightSize™ Particle Manufacturing Technology, is a ground-breaking solution for pharmaceutical particle development and production based on supercritical fluid technology. Overcoming many of the drawbacks of traditional micronization it is well suited to demanding applications, such as inhaled compounds, sparingly soluble compounds and biopharmaceuticals. As well as offering all the advantages of earlier supercritical fluid technologies it is also fully scalable.

The new GMP facility has been developed in collaboration with Galenica AB, an established Swedish CRO focused on pharmaceutical formulation. Manufacturing will be carried out by Galenica at the company’s state-of-the-art GMP suites in Malmö, Sweden.

About Karolinska Development

Managing one of the largest portfolios of life science research companies in Europe, Karolinska Development is a new type of pharmaceutical company focused on filling the innovation gap within the industry. Using a unique, highly cost-effective model Karolinska Development commercializes internationally renowned life science innovations, developing the medical products of the future. Professionals in business development and management, supported by an extensive network of experienced technical specialists, ensure fast and efficient development from concept to proof-of-principle. By taking the lead investor position in seed-stage companies Karolinska Development is able to use its long-term vision to rapidly build value from high-risk opportunities.

KAROLINSKA DEVELOPMENT

Karolinska Development is located at the Karolinska Institute Science Park, Sweden.
www.karolinskadevelopment.com

About XSpray

XSpray Microparticles AB is a Swedish life science technology company with in-depth knowledge of supercritical fluid technology, solid state properties, formulation science and the drug development process. The Company's cutting-edge platform technology – RightSize™ Particle Manufacture – uses supercritical fluid as an antisolvent for controlled precipitation of an active pharmaceutical ingredient/drug substance. The technology not only provides a superior process to traditional methods but also delivers better quality pharmaceutical particles, from discovery to production.

The process yields consistent powder particles in terms of size, shape and morphology that simplify formulation and can be incorporated into a variety of dosage forms, such as tablets, capsules and inhalation systems. RightSize Particle Manufacture addresses unmet therapeutic needs by enabling the development of drugs with enhanced delivery options, such as faster onset of action, and by adding innovative properties that truly benefit patients.

A key advantage of RightSize Particle Manufacture is that it can be effectively scaled up to production volumes, making it an important breakthrough in the manufacture of pharmaceutical particles.

XSpray Microparticles has its headquarters and development laboratories in Stockholm, Sweden, and offers GMP production at a state-of-the-art GMP manufacturing facility in Malmö, Sweden.
www.xspray.com

About Galenica

Galenica is a pharmaceutical technology CRO located in Malmö, Sweden. The company offers preformulation and formulation, analysis, stability studies, documentation (CMC), GMP production together with project management. Galenica is authorized and audited by the Swedish Medical Agency for GMP production of clinical trial material for Phase I-III. The company has broad skills and experience in development projects and manufacturing of pharmaceutical preparations, comprising the most common types of dosage forms. Galenica can assist within all phases of a project, from the identification of an efficacious substance until a complete pharmaceutical is in commercial production.

www.galenica.se

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