



## **XSpray launches GMP production facility**

### **XSpray Microparticles Launches High Quality Particulate GMP Manufacturing to US and EU Regulatory Standards.**

*Stockholm, Sweden – August 20, 2009.* XSpray Microparticles AB, a life science technology company, today announced the launch of its new 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.

XSpray's RightSize Particle Manufacturing Technology, a ground-breaking solution for pharmaceutical particle development and production is 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. 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.

XSpray's CEO, Per Andersson, said, "We are extremely pleased to have this facility in place, we can now satisfy our customers' needs for GMP material. This also proves the technology can be scaled-up, an important step towards developing full pharmaceutical manufacturing capabilities." Dr. Andersson continued, "We are very pleased with this collaboration with Galenica.

Galenica's CEO, Ronnie Wallin, added, "Testing the technology went very smoothly and we established a production capacity that meets clinical study requirements. Our facilities comply with both EU and US regulatory standards and we are now able to start manufacturing for XSpray's customers. In addition to manufacturing, we also provide packaging and release testing services."

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### **About XSpray**

XSpray Microparticles AB is a 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. Find out more at: [www.xspray.com](http://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. For more information see: [www.galenica.se](http://www.galenica.se)