PRESS RELEASE

First GMP clinical batches of a StaniTab® Active Pharmaceutical Ingredient

StaniPharm today announces it has manufactured clinical batches of a highly potent drug nanosized according to the StaniTab® supercritical fluid technology.

Champigneulles, France, April 8, 2015

StaniTab® is an innovative crystallization process exploiting the unique properties of supercritical CO_2. Crystalline nanoparticles produced by this bottom-up technology are developed for the formulation of poorly soluble drugs for which they offer an enhanced bioavailability.

StaniPharm had started in 2013 a contract R&D study for a confidential customer which aimed at developing such nanocrystals for the oral administration of a high-potency drug. Positive preclinical results have been gathered by this customer with tablets incorporating this challenging active pharmaceutical ingredient nanosized by the StaniTab® technology.

So as to support this customer in the development of this innovative product, StaniPharm has produced for the first time StaniTab® clinical batches in compliance with the Good Manufacturing Practices (GMP).

This success now allows StaniPharm to propose to its partners its whole supercritical fluid technology platform from the earliest R&D stages to the manufacturing of clinical trial materials.

StaniPharm has been developing since 2010 technological solutions to meet challenges of the life science industry, particularly in the area of active substances crystallization and purification of drug substances, drug products and polymers.

At its Champigneulles facility, StaniPharm team operates supercritical fluid units for particle design, extraction and purification, an analytical development and quality control laboratory and clean rooms for the manufacturing of clinical materials.

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