

STRATEGIC RESPIRATORY STEROID PARTNERSHIP DELIVERS

PARTICLE ENGINEERED AND DESIGNED-FOR-PURPOSE cGMP API NOW AVAILABLE FOR WIDE RANGE OF ORIGINATOR AND GENERIC RESPIRATORY PRODUCT ENABLEMENT

Prosonix Ltd (Oxford, UK) and **Sterling Srl** (Perugia, Italy) are delighted to announce the successful GMP commercialisation of Prosonix world leading respiratory particle engineering technology at Sterling's FDA approved facilities in Perugia.

This success follows over two years of strategic co-operation between the two companies which combines Prosonix acknowledged leadership in the particle engineering of complex respiratory products and Sterling's position as Europe's leading independent steroid producer.

The particle engineered API is now embedded in a range of world-wide Client projects in MDI, DPI and Intranasal presentations. In addition, the Sterling partnership represents one of the key underpinnings of Prosonix "Own Product" development programs.

Sophisticated control of physicochemical properties such as size, shape, crystallinity, and inter-particulate forces are fundamental to the enablement of all inhalation products, be they Originator, Branded Generics, and particularly so in the case of Directly Substitutable Generics or. Only by pursuing a design-for-intent and particle engineering led approach can the key formulation performance success parameters such as stability and dose content uniformity across an extended shelf life be tightly controlled or tailored at will.

Customers, Industry and Regulators alike are increasingly acknowledging that historic techniques such as jet milling are simply no longer suitable for potent respiratory products and a step change in manufacturing operation is required to meet today's modern and exacting quality standards. Jet-milled API is often highly variable and highly amorphous which leads to unnecessarily complex processing resulting in products with significant dose-to-dose variability with an unknown shelf life.

Commenting on the announcement David Hipkiss, Prosonix CEO said,

"This is yet another key milestone for Prosonix delivering further confidence in our ability to commercialise our proprietary technology in support of our key focus in high value respiratory product development. Sterling have shown themselves to be an exemplary company in all aspects of our relationship to date and I am certain that they will remain a key and trusted partner for many years to come."

Adding his comments Simone Ferlin, Sterling CEO said

"By integrating the Prosonix technology, together we have been able to introduce novel, high performance, particle engineered API into the respiratory market to support an unmet, pressing and growing industry need. This symbiotic partnership provides significant differentiation for both Sterling and Prosonix, but most importantly provides Clients with the surety and quality of steroids that delivers the optimum solution for the complex respiratory challenges."

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