



PROSONIX LAUNCHES NEW CO-CRYSTAL DEVELOPMENT AND PROCESSING SERVICE

FOCUS ON COMMERCIAL SCALE PRODUCTION POTENTIAL OF CO-CRYSTALS

31st August 2010

Prosonix (Oxford, UK) is delighted to announce the launch of a new co-crystal development and processing service, aimed specifically at the manufacturing of pharmaceutical co-crystals suitable for use in inhaled and oral medicine. Our proprietary technologies can facilitate co-crystal manufacture at any scale alongside controlled particle size distribution and high purity.

Prosonix technologies such as UMAX[®], DISCUS[®], and USOBR[™] have been successfully applied to the production of a significant number of co-crystals including for example carbamazepine:saccharin (1:1), carbamazepine:nicotinamide (1:1) and indamethacin:saccharin (1:1) co-crystals. The co-crystals produced are very typically of higher purity and with a defined particle size distribution compared with those obtained from standard crystallization techniques. In addition, solubility and dissolution properties of the APIs are significantly improved by co-crystallization. The techniques can be as equally applied for identifying new co-crystals.

In key contrast to traditional solution based co-crystallization, our novel approach overcomes the historic need for critical matching of solubility during nucleation and growth of the co-crystal. In addition the risk of crystallizing single components is significantly reduced. The stoichiometric composition of the components is maintained throughout the process, and the conditions for nucleation and growth of the co-crystal is generated within the process.

Commenting on the launch, Dr Graham Ruecroft, CTO, said:

'This is yet another demonstration of how Prosonix is using several years of learning to tackle another key emergent area of pharmaceutical development by designing protocols for controlled crystallization and manufacture of pharmaceutical co-crystals in a robust and efficient manner. The methods we have developed allow us to control both the fundamental co-crystallization and the desired particle size, whether micro-crystals for respiratory products or larger particles for oral delivery. We are confident that our manufacturing techniques have the potential to be used as the de facto first choice production method of pharmaceutical co-crystals in the future'

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Notes for Editors Correct as of 5 March 2010

About Prosonix Ltd

www.prosonix.co.uk

Based in Oxford UK, Prosonix's team of chemists and engineers combine to give Prosonix a unique multidisciplinary approach and competitive advantage to solve customers complex particle engineering and product problems, leveraging its proprietary intellectual property and patented ultrasonic processing equipment to deliver long term and sustainable value added solutions, enabling the cost effective manufacture of better medicines.

Prosonitron[®], Prosonix's world leading patented sonocrystallization process and reactor technology is already proven across scale, facilitating the Complete Crystallization Control[™] of many aspects of complex pharmaceutical crystallization processes, including control of crystal size, shape, purity, the selective production of polymorphs, enhancing both manufacturing productivity and ultimate formulation performance. New and proprietary process variants include DISCUS[™]-I and DISCUS[™]-M for the advanced particle engineering of microcrystalline active ingredients. In addition a new range of small scale SonoLab[™] equipment is now available for laboratory and kilo lab use. Prosonitron technology is increasingly being recognised as the *defacto* first choice in pharmaceutical API crystallization and isolation. In this regard, Prosonix announced in September 2008 that Pfizer Group Manufacturing had selected the Prosonitron technology for implementation at its primary manufacturing Ringaskiddy facilities in Ireland.

UMAX[®] and SAX[™] are proprietary *Solution-to-Particle* sonocrystallization processes technologies with world beating potential for inhalation drug delivery. These build on Prosonix core Prosonitron[™] technology. Both processes can produce highly engineered single and combination microcrystalline drug particles that are ideally suited for inhalation, without the need for destructive milling or micronisation processes. Prosonix have proven *in-vitro* that the resultant particles have better stability, formulation consistency, eliminates dose-to-dose variation and could exhibit potentially improved efficacy per unit dose than those made by other techniques. UMAX[®] is a new and proprietary process technology discovered and developed exclusively by Prosonix. Prosonix in-licensed the SAX[™] technology from the University of Bath on a world wide exclusive basis in February 2007. .

In January 2008 Prosonix in-licensed a novel particle rounding technology process patent (PRT) from Rafael Industries(Haifa, Israel) Importantly the process patent is already granted in key geographies and has wide ranging utility independent of the method of ultrasound delivery in secondary particle engineering, post initial crystallization and isolation. Key applications include the post crystallization particle rounding to improve product flowability and rheology, compressibility, and added concomitant benefits in formulation performance and assurance. Additional opportunities in taste masking, coating, and granulation are also emerging. Used in combination, the PRT and the proven Prosonix Prosonitron process and reactor technology represents an ideal solution to a range of common secondary pharmaceutical manufacturing problems.

Underpinning Prosonix's leadership in commercializable crystallization technology is CrystalGEM[™] and SonoLab[™]. Marketed in partnership with Chiralabs (Oxford, UK) the CrystalGEM[™] offering is a unique and award winning predictive crystallization service that significantly enhances crystallization screening productivity in pharmaceutical development. SonoLab[™] is a suite of designed for purpose small scale reactors that can be used by the laboratory chemist with confidence, knowing that a proven scale up method already exists. In October 2008, Prosonix announced a worldwide sole marketing partnership with Syrris (Royston, UK) positioning Syrris as the prime channel to market for the new SonoLab[™] range.

Complementing its market led internal R&D programs, Prosonix is engaged with several strategic partnerships with leading academic and technology institutions, including the University of Bath, University of Coventry, and the University of Leeds.

Prosonix is further supported by leading industrial and academic consultants including but not limited to Professor Rob Price (University of Bath, UK), Professor Kevin Roberts (University of Leeds, UK) and Professor Tim Mason (University of Coventry), and Dr Steve Nichols former Head of Inhalation at Sanofi-Aventis UK.

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