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## **Prosonix and Mylan Enter Into Global Licensing Agreement for Generic Versions of Inhaled Respiratory Products Flixotide® and Flovent®**

OXFORD, England and PITTSBURGH, April 15, 2014 /PRNewswire/ -- Prosonix, an innovative speciality pharmaceutical company developing a portfolio of inhaled *Respiratory Medicines by Design*, today announced that it has entered into a global licensing agreement with Mylan Inc. (Nasdaq: MYL), one of the world's leading global pharmaceutical companies, for its leading inhaled respiratory products, PSX1001 and PSX1050.

PSX1001 and PSX1050, which are the first products to emerge from Prosonix's innovative and proprietary particle engineering platform, are being developed as generic versions to GlaxoSmithKline's pressurised metered dose inhalers (pMDI) Flixotide® and Flovent®, respectively. Flixotide and Flovent contain the active ingredient fluticasone propionate, a potent inhaled corticosteroid, and are indicated for the treatment of asthma. According to IMS Health, Flixotide and Flovent had global brand sales of approximately \$1.3 billion for the 12 months ending Dec. 31, 2013. A first marketing authorisation application for PSX1001 is expected to be submitted in the European Union in 2014.

David Hipkiss, CEO and Co-founder of Prosonix, said: "Our agreement with Mylan for the global development and commercialisation of PSX1001 and PSX1050 is a major milestone that reflects the outstanding contribution of the whole Prosonix team. As a world leader in manufacturing and commercialising high-value, difficult-to-manufacture generics and with a growing respiratory franchise, we believe Mylan is the ideal partner to ensure PSX1001 and PSX1050 are a commercial success and a strong validation of our 'Respiratory Medicine by Design' philosophy."

Rajiv Malik, President of Mylan, commented: "We are very excited to enter into this agreement with Prosonix as it represents another development milestone in our global respiratory franchise, one of our key strategic growth drivers, and strengthens our portfolio of difficult to develop and manufacture products. Further, Prosonix's expertise in the development of inhaled respiratory products perfectly complements the strength of Mylan's respiratory R&D capabilities. We look forward to a successful collaboration with Prosonix in the coming years as we bring to market generic versions of Flixotide and Flovent around the world."

Under the terms of the licensing agreement, Prosonix will file PSX1001 in the EU and retain marketing rights in certain territories. Mylan has marketing rights for PSX1001 and PSX1050 in the U.S., Canada, Australia, New Zealand, India, Japan, the EU, Iceland, Liechtenstein, Norway, Switzerland, Turkey, Russian Federation and the Commonwealth of Independent States. All other terms of the agreement remain confidential.

*This press release includes statements that constitute "forward-looking statements," including with regard to the company's future growth and performance. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: the impacts of competition; changes in economic and financial conditions of the company's business; uncertainties and matters beyond the control of management; and the other risks detailed in the company's filings with the Securities and Exchange Commission. The company undertakes no obligation to update these statements for revisions or changes after the date of this release.*

### **About Prosonix**

[www.prosonix.co.uk](http://www.prosonix.co.uk)

Prosonix is an innovative speciality pharmaceutical company developing a portfolio of inhaled Respiratory Medicines by Design. Its investors include Entrepreneurs Fund, Gilde Healthcare, Gimv, Quest for Growth, Solon Ventures and Ventech.

Prosonix' proprietary particle engineering technology enables it to design and engineer mono and combination drug particles that precisely meet the specific requirements for inhalation, delivering assured formulation performance using simple, cost-effective devices for a range of generic, super-generic and novel products.

Prosonix' pipeline focuses on near- and long-term opportunities, and is further complemented by a select number of partnered respiratory programmes. The in-house pipeline includes:

- **PSX1001** and **PSX1050**, generic versions of GlaxoSmithKline's Flixotide<sup>®</sup>/Flovent<sup>®</sup> monotherapy containing fluticasone propionate, a potent ICS, in development for asthma in pMDI,
- **PSX2005**, a generic version of GlaxoSmithKline's Seretide<sup>®</sup> combination product consisting of fluticasone propionate and salmeterol xinafoate (a long-acting beta agonist (LABA)) in development for asthma and COPD in pMDI,
- **PSX1002**, a drug-only proprietary formulation of glycopyrronium bromide, a long-acting muscarinic antagonist (LAMA), currently in Phase 2 clinical studies for COPD in pMDI, and
- **PSX2000 MCP™ Series** novel dual and triple combination products (ICS/LABA, ICS/LAMA, LABA/LAMA, and ICS/LABA/LAMA) designed specifically for respiratory diseases and based on Prosonix proprietary Multi-component Particles™. Uniquely, MCPs™ do not require additional functional excipients, adjuvants, or suspension agents for optimal formulation performance from pMDI or Dry Powder Inhalers (DPI).

Current partnered respiratory programmes also include:

- **PX1439**, a generic LABA in pMDI
- **PX1442**, a generic LAMA in a capsule based DPI.

*Flixotide<sup>®</sup>, Flovent<sup>®</sup> and Seretide<sup>®</sup> are trademarks of the GlaxoSmithKline group of companies*

### **About Mylan**

Mylan is a global pharmaceutical company committed to setting new standards in health care. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 1,300 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately 40% of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in approximately 140 countries and territories. Our workforce of more than 20,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. But don't take our word for it. See for yourself. See inside. [mylan.com](http://mylan.com)

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