MonoSol Rx Submits New Drug Application for Tadalafil PharmFilm®

Company Remains On Track for Potential FDA Approval in 2017

November 28, 2016 08:30 ET | **Source:** MonoSol Rx

Warren N.J., Nov. 28, 2016 (GLOBE NEWSWIRE) -- MonoSol Rx, a specialty pharmaceutical company leveraging its PharmFilm® drug delivery technology to improve patient outcomes and to address unmet needs, today announced that it has filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for Tadalafil PharmFilm for the treatment of erectile dysfunction.

“The filing of the NDA for Tadalafil PharmFilm is a significant milestone for MonoSol Rx and provides further evidence of the world-class capabilities of our development team. This application follows the successful completion of a pivotal pharmacokinetic study and a productive meeting with the FDA earlier this year,” said Dan Barber, Vice President of MonoSol Rx. “We believe that our product is well-positioned to compete in the multi-billion dollar erectile dysfunction market, based on its status as the first alternative to tadalafil tablets to file for FDA approval and our strong protective portfolio of patents. We look forward to working through the review process as we bring this innovative product to market.”

Tadalafil is a PDE5 inhibitor currently marketed in pill form for the treatment of erectile dysfunction and benign prostatic hyperplasia (BPH) under the brand name Cialis®, and for treatment of pulmonary arterial hypertension under the brand name Adcirca®. Tadalafil PharmFilm will be offered in single pack doses and is expected to have several Orange Book listed patents upon approval.

MonoSol Rx is currently exploring partnership opportunities for Tadalafil PharmFilm and has engaged ESC Advisors, a division of KEMA Partners LLC, to manage the partnering process.

About MonoSol Rx

MonoSol Rx is a specialty pharmaceutical company leveraging its proprietary PharmFilm drug delivery technology to develop products that improve patient outcomes and address unmet needs. PharmFilm can benefit patients by improving the efficacy, safety, and compliance of pharmaceutical and over-the-counter products. MonoSol Rx 's leadership in film drug delivery is

FDA-approved products — Suboxone® (buprenorphine and naloxone) sublingual film and Zuplenz® (ondansetron) oral soluble film. For press releases and other company information, visit www.monosolrx.com.

Contact

MonoSol Rx
Jessica Patel
jpatel@monosolrx.com

The Ruth Group
Lee Roth
lroth@theruthgroup.com
(646) 536-7012