



PRESS RELEASE

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APR Applied Pharma Research s.a. ("APR") and Labtec GmbH ("Labtec") announce the European Approval of Ondansetron RapidFilm™, co-developed in partnership with MonoSol Rx ("MSRx") and licensed to BioAlliance Pharma SA ("BioAlliance") for EU countries after completion of a Decentralized Procedure in the major 16 EU countries.

Balerna (Switzerland), Langenfeld (Germany) and Warren (New Jersey)

BioAlliance received DCP approval in the major 16 European countries of Setofilm®, a film strip formulation containing 4mg and 8mg Ondansetron, co-developed by APR, Labtec and MSRx and licensed for marketing to BioAlliance. It is the first prescription drug product ever approved in a dosage form based on film strip technology on a worldwide basis.

The Ondansetron film strip will be launched soon by BioAlliance under the brand name Setofilm®. The product is indicated for the prevention and treatment of Chemotherapy- and Radiotherapy- Induced Nausea and Vomiting ("CINV") in adults as well as children aged equal or above 6 months, and the prevention and treatment of Post Operative Nausea and Vomiting (PONV) in adults and children aged equal or above 4 years. The dosage form is especially useful for patients having difficulties to swallow, like children or elderly patients.

The Ondansetron formulation is based on a novel and proprietary oral drug delivery technology platform and consists of a very thin polymeric film strip containing Ondansetron. The product has the size of 3 cm² and 6 cm² for the 4mg and 8 mg dosage, respectively. Once placed in the mouth, it dissolves in a few seconds and is swallowed with the saliva without the need of water. The Ondansetron film strip improves patient compliance by reducing swallowing difficulties experienced by many patients taking other oral Ondansetron formulations currently available.

The total market for CINV and PONV in the 7 major markets (Top 5 EU countries, US and Japan) was approx. US\$ 1,6 Billion in 2008, and Ondansetron is by far the best selling drug in this therapeutic class with total sales of about US \$ 700 Million during the same period (2008, Datamonitor). Investigational uses of the drug include Parkinson's Disease, Schizophrenia, Irritable Bowel Syndrome and several other applications. CINV and PONV alone are affecting about 2.3 Million people in the 7 major markets. This number is expected to grow to 2.5 Million by 2018. Children are more likely to develop CINV and PONV than mature patients.

The film strip formulation is expected to reach a significant market share in Europe.

APR, Labtec and MSRx are collaborating to promote the global development of oral film strips containing Ondansetron as well as other drug candidates.

"Oral Film Strips are a less invasive and straining way to administer Ondansetron since it is an oral dosage form not requiring any intake of water or pills, which may be considered as potential triggers of emesis. Therefore it is suited for any kind of patient but with specifically higher compliance for children and the elderly" said Paolo Galfetti, CEO of APR.

Ingo Lehrke, Managing Director of Labtec, stated "We are very enthusiastic about our thin film development being the world's first prescription product to receive approval. It is a great encouragement to continue, together with our partners, on the path of further film strip developments to provide patients with more improved therapy options."



A. Mark Schobel, president and chief executive officer of MonoSol Rx, stated, “MonoSol Rx, APR and Labtec truly understand the value that film drug delivery offers throughout the pharmaceutical industry. Given our shared expertise, this collaboration creates a unique opportunity to broaden the development reach for prescription film products. We look forward to leveraging the capabilities and skills of our partners APR and Labtec as well as the unique attributes of our film strip technology to advance several drug targets for film delivery.”

About APR Applied Pharma Research

APR Applied Pharma Research s.a. is a private, internationally oriented Healthcare company headquartered in Switzerland with a subsidiary in Charlotte (NC, USA) and concentrated in the research, development and licensing of innovative, value added and patented healthcare products. The company focuses its efforts in three major areas: development and licensing of selected, patented drug candidates based on proprietary oral and topical delivery systems; fund and finance of innovative Healthcare projects by providing a balanced mix of capital and know how; support to companies for the development of third party projects on a contract basis.

About Labtec

Founded in 1990, Labtec GmbH is one of the leading drug delivery development companies focusing on transdermal and topical patches, as well as fast dissolving oral films based on its proprietary Rapidfilm® technology. Labtec is a subsidiary of tesa SE – a member of the Beiersdorf group of companies - and represents tesa's pharmaceutical business. The company offers contract development and contract manufacturing of patches and oral film strips to the pharmaceutical industry.

About MonoSol Rx

MonoSol Rx is a specialty pharmaceutical company leveraging its proprietary PharmFilm® technology to deliver unique proprietary pharmaceutical drug films. PharmFilm® is designed to benefit patients by improving the convenience, efficacy, and compliance of new and currently marketed drugs. The Company's leadership in film drug delivery is supported by strong intellectual property, a portfolio of commercialized over-the-counter (OTC) drug products, and a development pipeline of prescription formulations based on PharmFilm® technology.

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