



APR Applied Pharma Research ("APR") and Labtec GmbH ("Labtec") announce the European approval of Zolmitriptan Oral Dispersible Film (ODF)

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

APR and Labtec announce to have received on February 8th, 2012, the marketing authorization through a decentralized procedure (DCP) in 15 European countries of Zolmitriptan ODF, a film strip formulation containing 2.5mg and 5mg Zolmitriptan . It is their second prescription drug product, after SetoFilm® (Ondansetron ODF), approved in Europe in a dosage form based on a film strip technology. The product is developed in collaboration with Warren, New Jersey based company Monosol Rx .

The DCP had Germany as Reference Member State and 14 Concerned Member States (Austria, Belgium, Denmark, Finland, France, Ireland, Italy, The Netherlands, Norway, Poland, Portugal, Spain, Sweden and Ukraine). The product will be manufactured at Labtec's production site in Hamburg, Germany. APR and Labtec are now proceeding with the national procedures to complete the registration process. The team of companies that developed Zolmitriptan ODF is now entering discussions with other pharmaceutical companies to find the best marketing and distribution partner for the product.

Concurrently, MonoSol Rx and APR are reviewing their options in the United States to complete the required steps to obtain Marketing Approval by the FDA under a 505(b) 2 procedure.

Zolmitriptan Oral Dispersible Film ("ODF") is a unique formulation of Zolmitriptan based on the RapidFilm® technology, an APR and Labtec's novel and proprietary oral drug delivery technology platform. The product consists of a very thin polymeric film strip containing the active ingredient. It has the size of 3 cm² and 6 cm² for the 2,5 mg and 5 mg dosage strengths, respectively. Once placed in the mouth, it dissolves in a few seconds and is swallowed with the saliva without the need of water. The Zolmitriptan ODF not only avoids the risk of aspiration but also improves patient compliance by reducing swallowing difficulties experienced by many patients taking other oral Zolmitriptan formulations currently available.

"The approval of the ODF form of Zolmitriptan proves once more that our technology performs well. The Oral Film Strip dosage form is a less invasive way to administer Zolmitriptan than regular tablets and does not require water, thus avoiding potential triggers of nausea and vomiting which are symptoms frequently accompanying migraines." said Paolo Galfetti, CEO of APR.

"This is the next step in the success story of our Orally Dispersible Film (ODF) based products; Zolmitriptan ODF is intended to be a more user friendly form of Zolmitriptan and provides significant advantages to patients, said Ingo Lehrke, Managing Director of Labtec.

Asked about the market rationales of the Orally Dispersible Film based products, Mark Schobel, CEO of Monosol RX said: "One of the key feature of Orally Dispersible Film products is to bring innovation to the market at a very competitive cost and this is the key for any pharmaceutical company that strives to differentiate from others".

Zolmitriptan is the top selling anti-migraine drug in the combined top five European markets, with total sales in excess of \$ 130 Million and an approx. 18% market share (Datamonitor, Aug 2010) and one of the leading triptans in the US, with sales in excess of \$ 200 Million. According to independent



studies and researches, nausea occurs in more than 90% of all migraine sufferers; nearly one third of these experienced nausea during every attack. Vomiting occurs in almost 70% of all migraine sufferers.

About APR Applied Pharma Research s.a.

APR is an independent, international and integrated Healthcare Company headquartered in Switzerland and focused on three major areas: Delivering, Funding and Supporting Innovation in Healthcare. In particular, APR develops and licenses innovative, value added and patented healthcare products and proprietary drug delivery systems primarily in the oral and topical fields; APR also invests in companies or early stage innovative projects and provides a balanced mix of equity funding and/or financing together with APR's development, scientific, technical, marketing, licensing and management skills and know how; finally, APR supports biotech and pharmaceutical companies in the development of new pharmaceutical projects by providing on a contract basis added value, consultancy and R&D services under contract using a General Contractor approach. APR has entered into licensing and partnership agreements with pharmaceutical companies in over 100 countries worldwide with international sales on a worldwide basis. For press releases and other company information visit: www.apr.ch

About Labtec GmbH

Founded in 1990, Labtec has quickly become one of the leading drug delivery development companies in the transdermal and topical patch arena, later also leading the market with fast dissolving oral films in Europe. Labtec's brand Rapidfilm® stands for the oral dissolvable film technology. The brand Transfilm® represents Labtec's transdermal and topical patch technology and all corresponding developments and products using this way of administration. Since 2008 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. In 2009, Labtec started operations at tesa's new 3,000 m² GMP manufacturing site for patches and oral films. In March 2011 the tesa production facility has been certified as GMP compliant by the health authorities. This now offers a fullfledged contract manufacturing of TDS and ODF finished products being produced under clean-room conditions and with high-standard production equipment. For press releases and other company information visit: www.labtec-pharma.com

About MonoSol Rx

MonoSol Rx is a specialty pharmaceutical company leveraging its proprietary PharmFilm® technology to deliver drugs in films. The Company's leadership in film drug delivery is supported by strong intellectual property, a portfolio of commercialized prescription and over-the-counter (OTC) drug products, a pipeline of prescription formulations based on PharmFilm® technology, and two recent FDA approvals - Zuplenz®, the first approved prescription oral soluble film for the prevention of chemotherapy-induced, radiotherapy-induced, and postoperative nausea and vomiting, and Suboxone® sublingual film, the first sublingual film product for the treatment of opioid dependence. For press releases and other company information visit: www.monosolrx.com

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