APR Applied Pharma Research ("APR") and Labtec GmbH ("Labtec") announce filing for approval in Europe of Zolmitriptan Oral Dispersible Film (ODF)

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Balerna (Switzerland), Langenfeld (Germany) and Warren (New Jersey)
APR, the drug developer and drug delivery technology provider headquartered in Balerna, Switzerland and its partner Labtec, the drug delivery technology developer headquartered in Langenfeld, Germany announce the submission of Zolmitriptan Oral Dispersible Film (ODF) for approval in Europe. The oral dispersible film strip formulation containing the renowned anti-migraine drug Zolmitriptan is the second prescription product based upon their RapidFilm® technology and is co-developed in collaboration with the Warren, New Jersey based Monosol Rx .

The first oral dispersible film strip product, Ondansetron ODF has already been approved in Europe under the brand name Setofilm® by BioAlliance Pharma on March 2010. Additionally, on July 2010 Monosol Rx announced the approval in the US of Zuplenz®, the Ondansetron ODF marketed by Strativa Pharmaceuticals, a division of PAR Pharmaceuticals Companies Inc.

The registration procedure of Zolmitriptan ODF started on November 8th, 2010 as decentralized procedure (DCP) with 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 full DCP procedure is expected to be completed by the second quarter of 2012. The product will be manufactured for Europe at Labtec´s production site in Hamburg, Germany.
Concurrently, the same partners are proceeding in the Unites States to complete the required steps to obtain Marketing Approval by the FDA. Filing of an IND is expected during Q1/2011 and submission of a 505(b)2 NDA procedure is expected by Q1/2012, thus targeting an FDA approval of the film strip product before patent expiry of the originator's product marketed under the Zomig® brand by Astra Zeneca.

The Zolmitriptan ODF is a very thin polymeric film strip with a size of 3 sqcm and 6 sqcm for the 2,5 mg and 5 mg dosage strengths, respectively. Once placed in the mouth, the ODF dissolves in a few seconds and is swallowed with the saliva without the need of water. The small, thin dosage form together with its ease of administration without the need of water make Zolimitriptan ODF the ideal take-away medicine, permitting instantaneous medication if the patient experiences a migraine attack .

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
APR is an independent, international and integrated Healthcare Company headquartered in Switzerland with a subsidiary in Charlotte (NC, USA) 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

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.

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. 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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