



APR Applied Pharma Research (“APR”) and Labtec GmbH (“Labtec”) announce the successful completion of the pivotal clinical study on Zolmitriptan RapidFilm[®], and its upcoming submission for registration in Europe.

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

APR Applied Pharma Research (“APR”), the drug developer and drug delivery technology provider headquartered in Balerna, Switzerland and its strategic partner Labtec GmbH (“Labtec”), the drug delivery technology developer headquartered in Langenfeld, Germany announce the successful completion of the pivotal clinical study and its upcoming submission for registration in Europe of their new investigational product Zolmitriptan RapidFilm[®], an oral dispersible film strip formulation of the well known anti-migraine drug Zolmitriptan, co-developed in collaboration with the Warren, New Jersey based MonoSol Rx .

Zolmitriptan Oral Dispersible Film (“ODF”) is a unique formulation of Zolmitriptan based on the RapidFilm[®] technology, a novel and proprietary oral drug delivery technology platform. The product consists of a very thin polymeric film strip containing the active ingredient. The product has the size of 3 sqcm and 6 sqcm 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 improves patient compliance by reducing swallowing difficulties experienced by many patients taking other oral Zolmitriptan formulations currently available. Filing in Europe for approval is expected in October 2010 through a Decentralized Procedure starting from one major EU country.

“This is the latest step in the success story of our Orally Dispersible Film (ODF) based products”, said Ingo Lehrke , Managing Director of Labtec. “The successful outcome of the in-vivo pivotal clinical study on Zolmitriptan ODF will be followed by the submission for registration in Europe in October 2010. These study results follow the recent approvals in Europe (March 2010) and in the US (July 2010) of the first ODF formulations of Ondansetron, developed in strategic partnership by APR, Labtec and MonoSol Rx. Ondansetron ODF was the first worldwide approval of a prescription product using this innovative drug delivery technology”.

“The development of the ODF form of Zolmitriptan”, said Paolo Galfetti, CEO of APR, “opens new important marketing opportunities with further upside potential, if the anticipated switch to OTC of the 2.5mg dosage of Zolmitriptan is accepted in the European countries. 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 migraine. Zolmitriptan ODF is intended to be a more user friendly form of Zolmitriptan. Expressions of interest from multiple European and US companies have been received for the granting of marketing licenses”.

“Similarly to the experience we had with the Ondansetron Oral Soluble Film (OSF) formulation, recently approved by FDA, we are expecting an expeditious process for the US approval of Zolmitriptan Oral Soluble Film”, says A. Mark Schobel, President and CEO of MonoSol Rx, “the submission of the Zolmitriptan OSF IND is planned for December 2010 and the filing for approval using a 505(b)2 procedure is expected by end of 2011, one year prior to the end of Zolmitriptan’s exclusivity in 2013”.



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 Applied Pharma Research s.a. 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 GmbH is one of the leading drug delivery 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.

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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