



**APR Applied Pharma Research ("APR") and Tesa Labtec gmbH ("Tesa Labtec") announce the launch of SETOFILM® Ondansetron Oral Dispersible Film in several European countries by Norgine.**

Balerna (Switzerland), June 24<sup>th</sup> 2013

After the launch of Zuplenz® by Vestiq Pharmaceuticals Inc. in USA and the launch of Ondissolve® by Takeda in Canada in late 2012, the Ondansetron Oral Dispersible Film is now also available in the European Markets under the brand Setofilm® after first launch made by our commercial partner Norgine in late May.

Ondansetron Oral Dispersible Film is the first prescription product approved in Europe and North America utilizing this novel dosage form developed by APR and tesa-Labtec in collaboration with Monosol RX, the developer of Zuplenz® Ondansetron film for the US market.

Setofilm™ (Ondansetron) is indicated for the prevention and treatment of Chemotherapy and Radiotherapy Induced Nausea and Vomiting ("CINV" and "RINV") in adults as well as children of 6 months or older, and the prevention and treatment of Post-Operative Nausea and Vomiting (PONV) in adults and children of 4 years or older. The dosage form is especially useful for patients with swallowing difficulties, such as children or elderly patients.

This 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 finished product has the size of 3 and 6 sqcm for the 4mg and 8 mg dosage strength, respectively. Once placed on the tongue, 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.

"The Oral Dispersible Film technology is well suited to improve patient compliance whenever a quick and seamless delivery may be considered a significant advantage to patients and caregivers", said Ingo Lehrke, Managing Director of tesa-Labtec.

"We strongly believe in the success of our Setofilm™ because of the quality of the product and the excellence of our marketing partners. We also believe this success will be replicated by our new RapidFilm formulation based on Zolmitriptan, the leading drug for migraine treatment, that is currently approved in most European countries and available for licensing" said Paolo Galfetti, CEO of APR.

**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](http://www.apr.ch)

#### **About Tesa Labtec GmbH**

Founded in 1990, Tesa 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. Tesa 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 Tesa 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 m<sup>2</sup> 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.tesa-labtec.com](http://www.tesa-labtec.com)

#### **About Norgine**

Norgine is a successful, independent European specialty pharmaceutical company that has been established for over 100 years and has a presence in all major European markets. In 2012, Norgine's net product sales were c€250 million and the company employs over a 1,000 people. Norgine's focus is the development and marketing of pharmaceutical products that address significant unmet clinical needs in therapeutic areas such as gastroenterology, hepatology, critical and supportive care.

The Company currently markets a range of products in various markets in its key therapeutic areas: MOVICOL® for the treatment of constipation and faecal impaction, MOVIPREP® a bowel preparation for use prior to any procedure that requires a clean colon, KLEAN-PREP® for large bowel preparation prior to colonoscopy or surgery, XIFAXAN® (XIFAXANTA™) for the treatment of travellers' diarrhoea and the reduction in recurrence of episodes of overt hepatic encephalopathy, ORAMORPH® for the treatment of moderate to severe pain associated with cancer and our supportive care portfolio: SETOFILM®, SAVENE®, DANTRIUM®, XEROTIN® and PROTHER®.

Norgine is active in research and development and currently has products in various stages of clinical development. Norgine manufactures most of its own products in Hengoed, UK and Dreux, France. For more information: [www.norgine.com](http://www.norgine.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](http://www.monosolrx.com)



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