



APR Applied Pharma Research s.a. ("APR"), Labtec GmbH ("Labtec") and Norgine BV ("Norgine") announce the signature of an exclusive licensing agreement under which Norgine will market and distribute Setofilm[™] Ondansetron Oral Dispersible Film ("ODF"), in Europe and selected non-European countries.

Release issued on January 18th, 2012

Norgine and APR, together with its joint venture partner Labtec, today announced that they have entered into an exclusive licensing agreement under which Norgine has acquired the commercialization rights in Europe and selected non-European countries in Middle East, Africa and Australasia, of Setofilm[™] the ondansetron orally dispersible film strip developed by APR and Labtec. Financial terms of the deal were not disclosed.

"We are very pleased to announce that Setofilm[™] will be marketed in Europe and also in other countries in Middle East, Africa and Australasia by Norgine, a company with recognized marketing and commercial strengths across the territory. We believe that Setofilm[™] nicely fits with Norgine's therapeutic focus in supportive care." said Paolo Galfetti, CEO of APR, "APR is proud to provide patients with a unique product that will help them in the management of these debilitating conditions."

Peter Stein, Norgine's CEO said "We are delighted to have acquired the rights to Setofilm across all the markets in which Norgine has a direct presence and to have entered this relationship with APR and Labtec. We believe the product offers real benefits to patients and as such is an excellent addition to our existing products in supportive care"

Setofilm[™] is already registered in 16 European countries. Setofilm[™] is the first prescription product developed as an "orodispersible film" form to be registered in Europe and has been developed by APR and Labtec in collaboration with Monosol RX, the developer of Zuplenz[®] ondansetron film for the U.S.

Setofilm[™] is indicated for the prevention and treatment of Chemotherapy- and Radiotherapy- Induced Nausea and Vomiting ("CINV" and "RINV") 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 who have difficulties swallowing, 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 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.

CINV and PONV alone are affecting about 2.3 million people in the 7 major EU markets. This number is expected to grow in the coming years. Children are more likely to develop CINV and PONV than mature patients. Ondansetron is the leader product in the management of severe conditions of nausea and vomiting.





About Norgine BV

Norgine is an independent, successful European specialty pharmaceutical company that has been established for over 100 years and has a presence in all major European markets. In 2010, Norgine's net product sales were €258 million. The Company employs over 1,200 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 and supportive care. The Company currently markets a range of products in various markets in its key therapeutic areas e.g., MOVICOL[®] for the treatment of constipation and faecal impaction, MOVIPREP[®] a bowel cleansing preparation, KLEAN-PREP[®] for bowel preparation prior to colonoscopy, XIFAXAN[®] for the treatment of travellers diarrhoea and ORAMORPH[®] for the treatment of moderate to severe pain associated with cancer. 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

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: <u>www.apr.ch</u>

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. 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: <u>www.labtec-pharma.com</u>

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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