



**APR Applied Pharma Research s.a. and Labtec GmbH announce Ondansetron Oral Dispersible Film (“ODF”) is now available for licensing in Europe and selected non European countries, after having received marketing authorization in most countries of Europe.**

*Release issued June 13th, 2011*

APR and Labtec have regained the marketing and commercialization rights of Ondansetron Oral Dispersible Film (“ODF”) together with the brand name “Setofilm®” after the termination of the former license agreement with the French Company BioAlliance which has refocused its activities towards other types of products. Ondansetron ODF is approved in 16 European countries and is ready to be marketed. APR and Labtec are in a position to offer marketing and commercialization rights for Ondansetron ODF in Europe and selected Non-European countries, either through global, regional or local license agreements.

“We are excited about this opportunity and we are now aggressively looking for commercial partners in the various countries of continental Europe with the right sale organization and marketing infrastructure able to maximize the product sale potential” says Paolo Galfetti, CEO of APR; “thanks to its specific drug delivery system and dosage form, we obtained in the countries of Europe full pediatric indications for the product”.

Ondansetron ODF 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 product 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.

This Ondansetron ODF formulation uses the Rapidfilm® technology, 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 cm<sup>2</sup> and 6 cm<sup>2</sup> 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. Therefore this dosage form improves patient compliance by reducing swallowing difficulties experienced by many patients taking other oral Ondansetron formulations currently available.

Sales of antiemetic and anti-nausea are expected to be 466 Million \$ in the top 5 European countries in 2012 with an expected CAGR of 2.0% till 2018. Ondansetron alone is expected to sell about 246 Million \$ in 2012 in the same countries with a 53% market share in values and 78% in volumes.

Ondansetron is the first 5-HT<sub>3</sub> molecule having become generic. The penetration rate of generics on total Ondansetron sales is expected to move up from 60% in 2012 to 66% in 2018 in the 5 top European countries. CINV and PONV alone are affecting about 2.3 Million people in the 7 major markets. This number is expected to grow to 2.5 Million by 2018. Children are more likely to develop CINV and PONV than mature patients.

The ODF formulation is expected to reach a significant market share in Europe.

**About APR Applied Pharma Research s.a.**

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](http://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. 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 m<sup>2</sup> GMP manufacturing site for patches and oral films. For press releases and other company information visit: [www.labtec-pharma.com](http://www.labtec-pharma.com)

#### **Contacts:**

APR Applied Pharma Research s.a.,  
Paolo Galfetti, CEO  
T: +41 91 6957020 or email to [paolo.galfetti@apr.ch](mailto:paolo.galfetti@apr.ch)

Labtec GmbH,  
Ingo Lehrke, Managing Director  
Tel: +49 2173 9735-0 or email to [ingo.lehrke@labtec-pharma.com](mailto:ingo.lehrke@labtec-pharma.com)