



APR Applied Pharma Research ("APR") and Labtec GmbH ("Labtec") announce the European approval of two new Oral Dispersible Film (ODF) based respectively on Olanzapine and Donepezil

Balerna (Switzerland), Langenfeld (Germany)

APR and Labtec announce to have received the marketing authorization through decentralized procedures (DCP) of their antipsychotic product Olanzapine ODF and of their Alzheimer disease product Donepezil ODF.

Olanzapine ODF is a film strip formulation containing 5mg, 10 and 15mg Olanzapine. The DCP had Germany as Reference Member State and 11 Concerned Member States (Austria, Belgium, France, Ireland, Italy, Netherland, Poland, Portugal, Spain, UK).

Donepezil ODF is a film strip formulation containing 5mg and 10mg Donepezil. The DCP had Germany as Reference Member State and Portugal and Spain as Concerned Member States.

During the progression of the national procedure necessary to complete the registration process, APR and Labtec will be entertaining discussions with pharmaceutical companies in order to identify the most suitable marketing and distribution partner for these products.

Olanzapine Oral Dispersible Film and Donepezil Oral Dispersible Film ("ODF") are unique formulations of Olanzapine and Donepezil based on the RapidFilm® technology, an APR and Labtec's proprietary oral drug delivery technology platform. The products consist of a very thin polymeric film strip containing the active ingredient. They have the size of 3cm² (5mg) 6cm² (10mg) and 9cm² (15mg; Olanzapine only), respectively. Once placed in the mouth, it dissolves in few seconds and is swallowed with the saliva without the need of water.

"The ODF formulations of Olanzapine and Donepezil are intended to help patients and caregivers to ensure that the proper daily dosage of these active principles is administered to the patient. Olanzapine and Donepezil ODFs share the same concept of compliance, a vision that puts the focus on schizophrenia, bipolar disorder and Alzheimer disease patients, who may be unable or reluctant in following the prescribed pharmaceutical therapies. The specific polymeric film strip form ensures caregivers the certainty of the dose intake in a more effective fashion than traditional tablet forms that could be held in the mouth and then spit out by the patient when left unattended by the caregivers", said Paolo Galfetti of APR.

"The RapidFilm® technology is well suited to improve compliance whenever a quick and seamless delivery may be considered a significant advantage to patients and caregivers" said Ingo Lehrke, Managing Director of Labtec.

Olanzapine, approved by the U.S. Food and Drug Administration (FDA) and most European countries for the treatment of schizophrenia and bipolar disorder, is one of the top selling drugs in the world.

Donepezil, approved by the U.S. Food and Drug Administration (FDA) and most European countries for the symptomatic treatment of Alzheimer's disease is a leading molecule in such treatment.

About APR Applied Pharma Research s.a.

APR is an independent, international and integrated Healthcare Company headquartered in Switzerland, which focuses 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 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. 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 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. 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.labtec-pharma.com

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