



## PRESS RELEASE

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APR Applied Pharma Research s.a. ("APR") and Labtec GmbH ("Labtec") announce the successful completion of the pilot bioequivalence study of their Donepezil RapidFilm<sup>TM</sup> further confirming the validity and adaptability of this innovative proprietary technology.

## Balerna (Switzerland) and Langenfeld (Germany).

"A few weeks after the positive results of the pivotal bioequivalence study for Ondansetron RapidFilm<sup>TM</sup>, which is now expected to become one of the first prescription film strip formulations ever to reach the market, the success of the pilot study on donepezil, our second product candidate under development with the RapidFilm<sup>TM</sup> technology is an important confirmation of our proprietary technology and know-how in the development of value-added Pharmaceutical Rx products" says Paolo Galfetti, CEO of APR.

"This further validation of the RapidFilm<sup>TM</sup> technology is extremely important because it strengthens the technology position as an attractive and cost-effective alternative, due to its efficacy, patient acceptance/compliance and price-competitive manufacturing process to currently available oral dissolving formulations" says Ingo Lehrke, Managing Director of Labtec.

Donepezil RapidFilm<sup>TM</sup> is a new oral formulation of the centrally acting reversible acetyl cholinesterase inhibitor Aricept® (Eisai). Donepezil's main therapeutic use is in the treatment of Alzheimer's disease where it is used to increase cortical acetylcholine. Donepezil is generally better tolerated than other molecules in its class, easier to use, and the drug with the largest number of well controlled clinical trials.

Donepezil RapidFilm<sup>TM</sup> is based on a novel proprietary oral drug delivery technology platform and consists of a very thin polymeric film strip incorporating and delivering donepezil in both 5 mg and 10 mg dosages. The Donepezil RapidFilm<sup>TM</sup> once placed in the mouth dissolves in a few seconds and is swallowed with the saliva. The Donepezil RapidFilm<sup>TM</sup> increases patient compliance by significantly reducing swallowing difficulties experienced by many patients taking donepezil formulations. Moreover, it ensures that the medicine is not rejected by uncooperative/difficult patients after it is placed in the mouth.

APR and Labtec are now working on fine tuning the formulation and the scale up of the product for subsequent pivotal bioequivalence study of the Donepezil RapidFilm<sup>TM</sup>. As with the Ondansetron Rapidfilm<sup>TM</sup> formulation, the EU registration strategy will follow the Decentralized Procedure with Germany being the reference country. In the United States an NDA application based upon a 505(b)2 procedure is being planned.

APR and Labtec are screening a wide range of candidates in several therapeutic areas for new in-house and collaborative development projects. "A huge variety of prescription products can be developed with the RapidFilm<sup>TM</sup> technology" says Dr. Armin Breitenbach, Director of Pharmaceutical





Development at Labtec. "Many potential applications exist in patients with swallowing difficulties due to age, disease or treatment."

## About APR Applied Pharma Research

APR Applied Pharma Research s.a. is a privately owned internationally oriented Drug Research & Development company headquartered in Switzerland. The privately held company focuses its efforts on the development of its own selected drug candidates (developed using APR proprietary technologies) as well as on the development under contract of third party pharmaceutical products and medical devices. Leveraging on its own technology platforms, R&D know-how, marketing and regulatory systems, APR is committed to create new sustainable value on its own as well as on third party products and projects.

The APR products and technologies are licensed to third parties for distribution and marketing. R&D activities are carried out directly or under contract. APR has signed licensing agreements with pharmaceutical companies in about 35 countries worldwide and its sales are almost totally achieved abroad.

**Labtec GmbH** is a privately owned development company, located in Germany. Labtec is focused on the development of drug delivery systems (transdermal delivery systems, buccal/gingival delivery systems, fast dissolving dosage forms) and contract analytics. It has licensing agreements as well as research and development partnerships with several large pharmaceutical companies throughout the world.

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