

PRESS RELEASE

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Title:

APR Applied Pharma Research s.a. (“APR”) and Labtec GmbH (“Labtec”) announce the successful completion of the Pivotal Bioequivalence study for their proprietary Ondansetron RapidFilm™

Balerna (Switzerland) and Lagenfeld (Germany).

On the basis of bioequivalence assessed in this pivotal study, therapeutic equivalence between Ondansetron RapidFilm™ and Zofran ODT® could successfully be demonstrated. The pivotal BE study also reconfirmed the positive safety results of a pilot study conducted in early 2007. Adverse events were very limited, indicating a well tolerated and comparable overall safety profile of the investigational APR-Labtec product Ondansetron RapidFilm™ and the reference product Zofran® Zydis® ODT.. However, from a more general safety perspective, Ondansetron RapidFilm™ does not contain Aspartame/phenylalanine, , therefore avoiding precautions required when administering drugs containing phenylalanine.

“We believe this is one of the most advanced development of a prescription film strip product”, said Paolo Galfetti, CEO of APR. “The RapidFilm™ form has all the features to become a most welcomed pharmaceutical form by patients and care providers because of its very high compliance and easiness to use. Ondansetron is an ideal candidate for the application of our proprietary film strip technology to a prescription drug. As we are moving rapidly with the registration process in the European and American markets with Ondansteron RapidFilm®, we are identifying partners with the capability to commercialize this product and maximize the value of this technology”.

„Ondansetron RapidFilm™” is a new oral formulation, directly competing with Zofran Zydis® Oro-Dispersible Tablets marketed in Europe as well as in the US by Glaxo Smith Kline. Its indications are: Prevention of Chemotherapy-Induced Nausea and Vomiting (CINV), prevention of nausea and vomiting associated with radiotherapy and prevention of Post-Operative Nausea and Vomiting (PONV).

Ondansetron RapidFilm™ is based on a novel proprietary oral drug delivery technology platform and consists of a very thin polymeric film strip incorporating and delivering ondansetron. The Ondansetron RapidFilm™ has the size of 3 cm² (4 mg dosage) and 6 cm² (8 mg dosage). Once placed in the mouth it dissolves in a few seconds and is swallowed with the saliva without the need of water. The Ondansetron RapidFilm™ increases patient compliance by reducing swallowing difficulties experienced by many patients taking oral ondansetron formulations. The technology is complemented by a very effective taste masking technology.

APR and Labtec are proceeding with filing of the application for registration in Germany which will be the Reference Member State for the EU Decentralized Procedure.. In the United States APR-Labtec plan to file an NDA application based upon the 505(b2) procedure.

The annual prescription market for oral ondansetron is worth \$ 1.2 billion in the US (30% of which comprised by the Zydys® ODT form) and approx \$ 100 million in the Top 5 European countries (41% of which taken by the Zydys® ODT form).

Ondansetron is by far the top selling 5-HT₃ antagonists (ondansetron, dolasetron, granisetron, tropisetron and palonosetron) used in the prevention and treatment of [nausea](#) and [vomiting](#) both in the United States and in the Top 5 European countries (where Ondansetron accounts for 67% of the total 5-HT₃ antagonists market).

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 and 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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