For Immediate Release
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APR Applied Pharma Research s.a. ("APR") and Labtec GmbH ("Labtec") announce positive results of the Ondansetron RapidFilm™ pilot bioequivalence study. Submission of registration dossier for fast dissolving oral film anticipated for Q4/2007

On March 2006, after the success of the previous Partnerships, APR has entered into a new strategic partnership with Labtec on the development and licensing of the RapidFilm™, an oral rapid-dissolving film technology.
The two companies are currently applying the RapidFilm™ technology to Ondansetron as active ingredient.

The bioequivalence for the AUCs of Ondansetron 8mg RapidFilm™ versus Zofran® 8mg Zydis® ODT has was demonstrated by a pilot bioequivalence study.
Following the administration of a single dose of 8mg Ondansetron to 6 healthy adults from Ondansetron 8mg RapidFilm™ (Investigational Product/APR-Labtec) and Zofran® 8mg Zydis® ODT (Reference Product/GlaxoSmithKline) AUCs passed the acceptance criteria.
Adverse events were limited, indicating the comparable safety of the investigation product Ondansetron 8mg RapidFilm™ to the reference product Zofran® 8mg Zydis® ODT and both the investigational and reference were safe and well tolerated.
Ondansetron 8mg RapidFilm™ does not contain Aspartame, while Zofran does, therefore there are no precautions for administer Ondansetron 8mg RapidFilm™ to phenylketonuric patients.
APR-Labtec will conduct a pivotal bioequivalence study with a higher number of subjects in early 2007 and plan to submit the registration dossier shortly thereafter.

RapidFilm™ is a novel proprietary oral thin film drug delivery technology platform consisting of a very thin polymeric film strip incorporating and delivering pharmaceutical active ingredients (alone or in combination): The RapidFilm has the size of a stamp and – once placed in the mouth – dissolves in a few seconds and is swallowed with the saliva without the need of taking water. The RapidFilm™ technology secures patient compliance by eliminating swallowing difficulties. The technology is complemented by a superb tastemasking technology as well as innovative packaging.

„Ondansetron RapidFilm" is a new oral formulation, generic to ZOFRAN® 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).
The new formulation rapidly disintegrates on the tongue and does not require water to aid dissolution and swallowing.
PONV affects approximately one third of patients and may lead to aspiration, dehiscence, esophageal rupture and increased costs if inadequately controlled.

Ondansetron has been utilized as antinausea in the treatment of vomiting induced in patients receiving chemotherapy.

APR is now in the process of securing licensing partners for this product on a worldwide basis.

The market of antiemetics and antinauseants in Europe is around 426 million of standard units with an average forecasted growth rate around +1,03% per year (2005 – 2010).
Before patent expiry, Ondansetron was within the top 20 selling branded drug in the US in 2005 with sale exceeding $839 million" (Source: Drug Topics, 19.06.2006).
The market of Ondansetron in the top five European countries (Germany, Spain, France, UK, Italy) is worth €65 million in 2006 (Data in Mnf. Prc IMS).

APR Applied Pharma Research s.a. is a privately owned internationally oriented Drug Delivery company with registered offices in Switzerland. It is focused in the research & development of innovative and patented drug delivery systems as well as innovative pharmaceutical products primarily for oral and topical administration. The APR products and technologies are licensed to third parties for distribution and marketing activities. R&D activities are carried out directly or under contract. APR has signed licensing agreements with pharmaceutical companies in about 60 countries worldwide and its sales are almost totally achieved abroad.

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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 Research and Development partnership agreements with several large pharmaceutical companies throughout the world.

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