

Oral Thin Film Drug Delivery Technology Leapfrogs Orally Disintegrating Tablet Technology

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Falls Church, VA (PR Web) January 25, 2006 -- Technology Catalysts International, consultants to the pharmaceutical industry, announced that its research on trends and developments in drug delivery has identified a breakthrough technology that accelerates pharmaceutical product market introductions by generic and drug delivery companies.

This development is particularly relevant to producers of drugs offered in the form of orally disintegrating tablets (“ODTs”), a \$2.4 billion market. They are now able to offer the same drug in the form of an “orally-dissolving strip,” also known as an Oral Thin Film (“OTF”), with the filing of an Abbreviated New Drug Application (“ANDA”) with the US Food and Drug Administration (“FDA”). This is a major cost of goods saver for generics.

The FDA has approved the change in dosage form for drug products as long as there are no questions about the safety or effectiveness of the product. This requires that the uses, dosage and route of administration of the proposed drug product are the same as the listed drug product. This was the basis on which Pepcid AC(R) could also be offered in the form of an OTF.

In Technology Catalysts’ recently-released report on “Orally Disintegrating Tablet and Film Technologies” (3rd Edition), the company identified over 15 companies actively developing OTF delivery technologies that enable the shift from a tablet form to a fast-dissolving and highly water-soluble wafer or film. In addition, the report identifies:

- Nine launched OTF pharmaceutical products
- Forty-seven OTF products in the pipeline being developed by 12 companies

This report discusses new developments from companies such as APR Applied Pharma Research S.A. (“APR”), a leading Swiss R&D company focusing on innovative drug delivery. In conjunction with Labtec GmbH, APR has developed a novel OTF technology called RapidFilm(TM).

Dr. Paulo Galfetti, Head of Licensing & Business Development states that RapidFilm offers unique potential to deliver a variety of drugs, particularly when a fast onset of action is required. Galfetti advises that this technology can be used with poorly soluble drugs. Classes of drugs that can benefit from delivery via the RapidFilm system include hypnotics, anxiolytics, antiemetics, NSAIDs and pain killers, 5HT1 agonists for migraine treatment, antiallergics, antacids, vitamins, minerals, and treatments for the oral cavity.

TCI’s report also details the technology programs of 25 companies active in the development of Orally-Disintegrating Tablet technologies and 17 active in the development of Oral Film technologies.

Technology Catalysts forecasts the market for drug products in oral thin film formulations to be valued at \$500 million in 2007 and could reach \$2 billion by 2010.



For additional information on this report, please contact Jared Hahn or visit www.technology-catalysts.com.

About Technology Catalysts International:

Technology Catalysts International (“TCI”) was founded in 1979 and provides consulting services in technology transfer and business research. The company specializes in technology licensing, technology assessment, and technology portfolio management. With a focus on pharmaceuticals, drug delivery, consumer healthcare, chemicals, and advanced materials/processes, TCI’s core consulting services are based on continuous monitoring of technological product development activities on a global basis.

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