For immediate release
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PLIVA Announces Approval for Ondansetron Hydrochloride ODT

PLIVA d.d. ("PLIVA") announced today that its partner on ondansetron hydrochloride (HCl) orally disintegrating tablets (ODT) in 4 mg and 8 mg strengths, Kali Laboratories, Inc. ("Kali"), a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc., has received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for the product, and that it has been awarded 180 days of marketing exclusivity for being the first to file an ANDA containing a paragraph IV certification for the product.

Under the terms of the agreement between the two companies, PLIVA Inc., PLIVA's wholly owned U.S. subsidiary, has exclusive rights to market, sell and distribute ondansetron HCl ODT in the U.S. The product will be manufactured by Kali and the companies will split profits from the sales of the product.

GlaxoSmithKline currently markets ondansetron HCl ODT under the brand name Zofran ODT®. The product is used for the prevention of nausea and vomiting associated with emetogenic cancer chemotherapy, certain radiotherapies, and the prevention of postoperative nausea and/or vomiting. Annual US sales of Zofran ODT® are approximately USD 225m.

Kali and Pliva Inc. are currently involved in litigation with GlaxoSmithKline. In July 2005, the U.S. District Court for the District of New Jersey issued a summary judgment ruling in GlaxoSmithKline's favor. Kali and Pliva Inc. are appealing the decision.

More information about PLIVA can be found at www.pliva.com.

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