Debiopharm announces U.S. NDA filing
of Trelstar® 6-month formulation
for locally advanced or metastatic prostate cancer

Lausanne, Switzerland, November 14, 2008 - Debiopharm Group (Debiopharm), a global independent biopharmaceutical development specialist focusing on serious medical conditions and particularly oncology, today announced that the New Drug Application (NDA) for the 6 month formulation of Trelstar® (triptorelin pamoate) has been accepted for filing by the United States (U.S.) Food and Drug Administration (FDA). Trelstar® is a luteinizing hormone releasing hormone (LHRH) agonist for the treatment of locally advanced or metastatic prostate cancer. Once approved, Trelstar® will be commercialised in the U.S. by Watson Pharmaceuticals, Inc.

"Last September we announced the filing of the product with the European Agencies, under the name Decapeptyl®. We are proud to have accomplished the simultaneous filings of Trelstar® and Decapeptyl® in both the U.S. and Europe, it's a great achievement for us," said Rolland-Yves Mauvernay, president and founder of Debiopharm Group. "This demonstrates our ability to work effectively not only with different regulatory agencies, but also different partners. Furthermore, our FDA inspected research development and production facility, Debio R.P., will produce both products for global distribution."

The NDA for the 6 month formulation of Trelstar® is supported by data from a phase III study on the efficacy and safety of two consecutive injections of triptorelin 6-month formulation in 120 patients with advanced prostate cancer. The results showed that 97.5% of patients achieved castrate levels of serum testosterone 28 days after the first injection and that 93% of the patients maintained serum testosterone levels below castrate level (defined as $\leq$ 1.735 nmol/L or 50 ng/dL) from week 8 to 48. These efficacy results are similar to those obtained previously with repeated administrations of the 1- and 3-month formulations of Trelstar®, which are already marketed by Watson Pharmaceuticals, Inc.

About Debiopharm Group
Debiopharm Group is a global biopharmaceutical development specialist that in-licenses promising biologics and small molecule drug candidates. Debiopharm develops its products for global registration and maximum commercial potential for out-licensing to pharmaceutical partners for sales and marketing.

Debiopharm independently funds the worldwide development of all of its products while providing expertise in pre-clinical and clinical trials, manufacturing, drug delivery and formulation, and regulatory affairs.

Founded in 1979 and headquartered in Lausanne, Switzerland, Debiopharm has developed three products with global combined sales in excess of $2.65 billion in 2007.
For more information on Debiopharm Group, please visit: www.debiopharm.com.

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