DEBIO PHARM S.A.

INFORMATION

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FOR IMMEDIATE RELEASE

SWISS DRUG DEVELOPER DEBIOPHARM ANNOUNCES FDA APPROVAL OF TRELSTAR™ LA FOR THERAPEUTIC USE

Lausanne, Switzerland, July 5, 2001 – The Swiss-based pharmaceutical development company Debiopharm S.A., part of the Debio group, today announced that the FDA has granted marketing authorization for Debiopharm's luteinizing hormone releasing hormone (LHRH) agonist, triptorelin pamoate, TRELSTAR™ LA, to treat advanced stage prostate cancer. TRELSTAR™ LA is a controlled release formulation of triptorelin which delivers triptorelin continuously over a period of three months after intramuscular injection.

Extensive clinical studies comparing the effectiveness of the already approved one-month controlled release formulation of triptorelin (TRELSTAR™ DEPOT 3.75mg) and the new three-month formulation of triptorelin (TRELSTAR™ LA 11.25mg) in men with advanced stage prostate cancer have proven that three-monthly administrations of triptorelin induce and maintain castration levels of serum testosterone as effectively as monthly injections. TRELSTAR™ LA is approved in two different presentations: As a vial alone, containing triptorelin pamoate to be reconstituted in sterile water for injection, or as TRELSTAR™ LA DebioClip™ single-dose delivery system, developed by Debiotech, Switzerland, consisting of a vial containing triptorelin pamoate and a pre-filled syringe containing 2 ml sterile water for injection. DebioClip™ is an innovative device for easy and safe lyophilized drug reconstitution, and avoids accidental exposure to needlesticks by healthcare workers. TRELSTAR™ LA has optimal patent life protection in the United States.

During the pivotal clinical trial, which proved that the three-month formulation of triptorelin pamoate is as effective as the monthly formulation, secondary objectives included regression of pain, mean change in Quality of Life scales throughout the treatment period, and testosterone pharmacodynamics. Patients treated with triptorelin pamoate used fewer analgesics after the start of treatment and, overall, patients gained on average 5 kg in body weight. The local tolerance of the injections was excellent and TRELSTAR™ LA was well tolerated.

"Our three-month injectable formulation of triptorelin, TRELSTAR™ LA, represents a significant benefit to patients in terms of comfort and quality of life and demonstrates Debiopharm's proven expertise in bringing drugs to market in the United States and Canada, as well as in Europe," says Dr. R.-Y. Mauvernay, founder and President of the Debio Group, which includes Debiopharm, Debio R.P. and Debioclinic. "Debio's knowledge and expertise in both drug development and controlled release systems has allowed us to develop this formulation."

"We are very proud of the approval of TRELSTAR™ LA, which is manufactured in a state-of-the-art facility in Switzerland using our proprietary solvent-free process, developed specifically for this product," comments Dr Piero Orsolini, President and CEO of Debio R.P. "We are working on new formulations able to release triptorelin over longer periods, other advanced drug delivery systems for proteins and peptides, as well as other therapeutic agents."

Prostate cancer is the most common type of cancer found in American men, other than skin cancer. The American Cancer Society estimates that there will be about 198,100 new cases of prostate cancer in the United States in 2001. One hundred and ten men in every 100'000 will develop prostate cancer.

Debiopharm has a successful track record in bringing new chemical entities to the market in Europe and the United States. The monthly formulation of triptorelin is currently marketed in over 80 countries for prostate cancer, endometriosis, fibromyoma, breast cancer and precocious puberty. It is the market leader in Southern Europe and Brazil. The worldwide LHRH agonist market is worth approximately US$ 1.4 billion. Debiopharm also has successfully developed oxaliplatin, the first diamine-cyclohexane platinum complex and a third generation platinum series, presently registered and commercialized in major European countries, Latin America and Asia for the treatment of advanced colorectal cancer. Debiopharm's vapreotide, a somatostatin analog used in the treatment of bleeding oesophageal varices, has completed Phase III and is currently under review for registration in Europe.

Specialized in oncology, hormonal and niche products for serious medical conditions, Debiopharm is the preferred partner of research institutions, pharmaceutical and biotech companies who seek to successfully develop their drug. Debio Recherche Pharmaceutique (Debio R.P.), Debiopharm's sister company, is a leading world player in the research, development and manufacturing of polymer-based controlled-release injectable formulations for peptides and proteins, including proprietary technologies suitable for other therapeutic modalities such as soluble polymer drug conjugates for parenteral administration. Debio R.P. carries out industrial scale up under current good manufacturing practice (cGMP) and is FDA inspected.

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