

## ***PRESS RELEASE***

### **DEBIOPHARM'S ELOXATIN<sup>®</sup> (OXALIPLATIN) AWARDED PRIX GALIEN IN FRANCE FOR INNOVATIVE CANCER THERAPY**

Lausanne, Switzerland, June 3, 2004 – Debiopharm S.A., the independent drug-development company specialising in oncology, endocrinology, CNS and niche diseases today announced that Eloxatin<sup>®</sup> (oxaliplatin), was awarded the prestigious 2004 Prix Galien in France for the treatment of advanced colorectal cancer.

This is the second time the Prix Galien is awarded to a Debiopharm product. Decapeptyl<sup>®</sup> (Trelstar<sup>®</sup> in the US), the first molecule to be successfully developed by Debio is an analog of gonadotrophin hormone releasing hormone for the treatment of prostate cancer and endometriosis, also received the Prix Galien.

Oxaliplatin, a new generation of platinum derivatives discovered by Prof Kidani in 1976 at Nagoya University in Japan, was licensed-in and developed by Debiopharm for the treatment of advanced colorectal cancer.

Oxaliplatin has been approved as an anticancer agent in over 60 countries worldwide and is currently marketed as Eloxatin<sup>®</sup> in Europe and in the US, by Sanofi-Synthélabo, with whom Debiopharm signed a license agreement in 1994. Eloxatin<sup>®</sup> is now the leading therapy for the treatment of colorectal cancer and Sanofi-Synthélabo's number three product, with sales of 824 million euros in 2003. Debiopharm's licensee in Japan, Yakult Honsha submitted a registration dossier in Japan in March 2004.

Under Debiopharm's development programme, Eloxatin<sup>®</sup> received the first marketing approval in France for the second line treatment of metastatic colorectal cancer in April 1996 and two years later received approval for first line treatment. Clinical trials, involving over 3000 patients treated with oxaliplatin, were performed by Debiopharm at Debioclinic, Debiopharm's Paris-based Contract Research Organization (CRO) specialized in oncology. In July 1999, following these trials, Eloxatin<sup>®</sup> was approved for the first line treatment indication in major European countries, through a mutual recognition procedure.

In January 2004, Eloxatin<sup>®</sup> was approved in the US for the 1<sup>st</sup> line treatment of metastatic colorectal cancer, it was also submitted in the US and Europe for the adjuvant treatment of patients with colon cancer, and it completed a mutual recognition procedure in Europe for the full treatment of metastatic colorectal cancer.

“Eloxatin<sup>®</sup> winning the Prix Galien, is a significant achievement and we are very proud to be in the league of the previous winners of the award, including Glivec<sup>®</sup> and Herceptin<sup>®</sup>. Also thanks to Sanofi-Synthelabo’s scientific and commercial contribution, Eloxatin<sup>®</sup> is now a well-known therapy globally.” said Rolland-Yves Mauvernay, President and CEO of Debiopharm. “This shows that creative and entrepreneurial drug development companies like Debio are capable of bringing to the world, a truly important medicine that benefits millions of patients. Winning this prestigious prize twice confirms the quality and competence of the Debio teams. ”

### **About the Prix Galien**

Named after the ancient Roman philosopher and teacher Claudius Galenus (AD 131-201), who is generally recognised as the ‘father of modern pharmacology’, the Prix Galien is an internationally recognised award, founded in France in 1969 by French pharmacist Roland Mehl and adopted by other countries - including Belgium, Canada, Germany, Italy, Portugal, Spain, Switzerland, the Netherlands, the USA and the United Kingdom.

The award is given to a new, genuine, innovative product offering therapeutic advantages over already existing treatments. A distinguished and independent panel of judges selects the winner, based on the innovative aspect and therapeutic advantages of its product.

### **About Debiopharm**

Debiopharm, founded in 1979 in Lausanne, Switzerland, focuses on evaluating compounds with promising *in-vivo* results in animals, to in-license, develop for global registration, and out-license to sales and marketing pharmaceutical partners. Debiopharm’s major commercial successes to date are Eloxatin<sup>®</sup>, one of Sanofi-Synthelabo’s leading marketed products, Decapeptyl<sup>®</sup>, the leading product of Ipsen in Southern Europe, and Trelstar<sup>®</sup>, with combined sales estimated to be in excess of \$1.8bn in 2004.

Debiopharm is one of an established group of three complementary companies, Debiopharm, Debio R.P. and Debioclinic, with a successful track record in developing, registering and out-licensing innovative therapeutics. Debio R.P. is a leader in polymer-based controlled release technologies that allow certain drugs like proteins, peptides and anti-cancers to be delivered in customised, sustained-release formulation. From its FDA-inspected manufacturing facility in Martigny, Switzerland, Debio R.P. also conducts feasibility studies, formulation selection, optimisation, scale-up and cGMP manufacturing from clinical trial supplies to commercial scale. Debioclinic is a contract research organisation, specialised in oncology and dedicated to clinical development, providing regulatory, biometric and clinical support in line with cGCP.

For more information on Debiopharm, please visit our website at [www.debio.com](http://www.debio.com)

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