

## ***PRESS RELEASE***

### **FOR IMMEDIATE RELEASE**

#### **YAKULT HONSHA FILES INITIAL SUBMISSION FOR MARKETING AUTHORISATION OF DEBIOPHARM'S OXALIPLATIN IN JAPAN**

**Lausanne, Switzerland, March 4, 2004** - Debiopharm S.A., the independent drug-development company specialising in oncology, endocrinology and niche products, today announces that Yakult Honsha Co., Ltd has filed an initial submission for marketing authorization of oxaliplatin in Japan, with the Ministry of Health, Labor, and Welfare, the Japanese equivalent of the US Food and Drug Administration (FDA). Oxaliplatin, a new generation of platinum derivatives discovered 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, Debiopharm's licensee. Eloxatin<sup>®</sup> is the leading therapy for the treatment of colorectal cancer and Sanofi-Synthélabo's number three product, with sales of €824 million in 2003.

In April 1996, Eloxatin<sup>®</sup> received marketing approval in France for the second line treatment of metastatic colorectal cancer and two years later received approval for first line treatment. Clinical trials, involving over 3000 patients treated with oxaliplatin, were performed 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.

On the 9<sup>th</sup> of January 2004, Eloxatin<sup>®</sup> was approved in the US, for the first line treatment of metastatic carcinoma of the colon or rectum, after an approval in August 2002 for second line treatment in patients. On the 19<sup>th</sup> of January 2004, Eloxatin<sup>®</sup> was submitted in the US and in Europe for the adjuvant treatment of colon cancer.

In 1997, Debiopharm concluded a license agreement with Yakult Honsha, to start a co-development of oxaliplatin in Japan. A Phase I study was initiated in June 1999 and a Phase II study began in April 2001.

“Our success is based on our capability and vision in identifying and developing new chemical entities,” said Rolland-Yves Mauverney, President and CEO of Debiopharm. “It is important that we select good commercial partners and continuously work on life-cycle management strategies. Together with Yakult we look forward to bringing a proven therapy to Japanese patients.”

## 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)

### Debiopharm Contacts

Mrs. Kim Bill  
VP Business Development & Licensing  
Debiopharm S.A.  
Tel.: +41 21 321 01 11  
Fax: +41 21 321 01 69  
kbill@debio.com

### Additional Media Contacts

#### In London

Maitland Noonan Russo  
Brian Hudspith  
Phone: +44 (0)20 7379 5151  
bhudspith@maitland.co.uk

#### In New York

Euro RSCG Life NRP  
Emily Poe  
Assistant Vice President  
Phone: +1 212 845 4266  
emily.poe@eurorscg.com