



# PRESS RELEASE

### FOR IMMEDIATE RELEASE

## DEBIOPHARM S.A. AND DYAX CORP. GRANTED EUROPEAN ORPHAN DRUG STATUS FOR EPI-hNE4 (DX-890) FOR CYSTIC FIBROSIS

Lausanne, Switzerland and Cambridge, Massachusetts (USA), July 29, 2003 – Debiopharm S.A. (Debiopharm) and Dyax Corp. (NASDAQ: DYAX) today announced that they received European orphan drug designation from the Commission of the European Community for the Engineered Protein Inhibitor of human Neutrophil Elastase (EPI-hNE4), or DX-890, for the treatment of cystic fibrosis (CF).

European orphan drug designation is granted for products that are intended to treat life-threatening or chronically debilitating conditions affecting no more than 5 in 10,000 persons. Further criteria include the ability of the product to provide significant patient benefit over available treatment, or to fill an unmet medical need where no other treatment exists. The Commission for the European Community concluded that DX-890 meets the orphan drug requirements for the treatment of cystic fibrosis, a genetic disease affecting approximately 1.3 in 10,000 people in Europe. CF is a chronically debilitating and life threatening condition and although satisfactory methods of treatment of the condition have been authorized in the European Community, the Commission for the European Community has indicated that Debiopharm provided justification that DX-890 may offer a significant benefit to those affected by the disease.

Orphan drug status of DX-890 in Europe can confer numerous benefits to its development, including clinical protocol assistance and advice, reduced registration fees when filing for product approval and, upon marketing authorization, marketing exclusivity for a period of up to 10 years.

"We are very happy to receive our first European orphan drug status for DX-890," said Dr. R.-Y. Mauvernay, founder and CEO of Debiopharm. "This is another milestone in the development of our product and it will facilitate our decision-making thanks to the administrative assistance provided by the health authorities."

"DX-890 is the second of Dyax's compounds in clinical development to receive orphan drug designation, and we're very pleased that the European regulatory authorities recognize the potential of DX-890 to provide a treatment alternative to patients suffering with cystic fibrosis. We believe that there are significant markets for drugs to treat orphan indications, and are committed to advancing DX-890 in collaboration with our colleagues at Debiopharm," commented Henry E. Blair, Chairman, President and CEO of Dyax Corp.

#### **About cystic fibrosis**

Mutations in the cystic fibrosis gene cause the body to produce an abnormally thick, sticky mucus that clogs the lungs and leads to life-threatening lung infections. Inflammation in the airways of CF patients is characterized by persistent and excessive neutrophil infiltration, which release large quantities of destructive oxidases and proteases, including human neutrophil elastase (hNE). Inhibition of hNE allows control of the inflammatory process early

in the course of the disease, and may limit the damaging effects of excessive inflammation, thus delaying progression of pulmonary deterioration and potentially decreasing mortality.

#### About DX-890

DX-890 is a highly specific and potent inhibitor of hNE and may act as a novel anti-inflammatory agent to target neutrophil-related inflammation. A collaborative Phase IIa open label study, conducted by Debiopharm in 25 adult CF patients confirms the tolerability and pharmacological effect of DX-890 on the inhibition of human Neutrophil Elastase (hNE) in the lungs of CF patients, when administered as a nebulised formulation. The results of the study show that with a 30mg/3ml dose of DX-890, complete inhibition of hNE was observed in 10 out of 19 patients (53%) and partial inhibition was observed in 5 out of 19 patients (26%). The total response rate was 79%.

Additional Phase II studies of DX-890 are planned in adult CF patients. One of the studies will take place in Germany, with a nebulized formulation of DX-890 to evaluate the reduction of the concentration of surrogate markers of inflammation, using broncho alvealoar lavage (BAL) as a means of measuring effect. Another study to demonstrate clinical benefit and to identify DX-890 dosing for a Phase III trial will also be conducted.

A European Phase IIa study of DX-890 in CF children and adolescents was initiated in 2002.

## Debiopharm S.A.

Debiopharm, Debio R.P. and Debioclinic are an established and proven group of three synergistic and complementary companies, that have a successful track record in developing, registering and ensuring that new chemical entities are brought to market both in Europe and in the United States. Products successfully registered and launched include oxaliplatin for advanced colorectal cancer and triptorelin pamoate for prostate cancer, both market leaders in their therapeutic areas. Specialized in oncology, hormonal and niche products for serious medical conditions, Debiopharm is a partner of research institutions, pharmaceutical and biotechnology companies who seek to develop and register their drugs. 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 cytotoxic-drug conjugates for parenteral administration. Debio R.P. also carries out scale-up under current good manufacturing practice (cGMP) and has an FDAinspected plant. Debioclinic, the third Debio company, is a contract research organisation fully dedicated to clinical development. For more information on Debiopharm, please visit its website at www.debio.com.

#### Dyax Corp.

Dyax Corp. is a biopharmaceutical company principally focused on the discovery, development and commercialization of therapeutics for inflammatory conditions and in oncology. Dyax currently has two recombinant proteins in clinical development, DX-88 and DX-890. DX-88 is being studied in phase II clinical trials for the treatment of hereditary angioedema in a joint venture with Genzyme Corporation. Dyax is also studying DX-88 in a phase I/II clinical trial for use during cardiopulmonary bypass surgery. DX-890 is being studied in phase IIa clinical trials for the treatment of cystic fibrosis in collaboration with Debiopharm, S.A. Dyax utilizes its proprietary phage display technology to rapidly identify a broad range of recombinant protein, peptide, and fully human monoclonal antibody compounds that bind with high affinity and specificity to targets of interest, with the objective of selecting those compounds with the greatest potential for advancement into clinical development. Dyax leverages broadly its core phage display technology through revenue generating licenses and collaborations in therapeutics and in non-core areas of affinity separations, diagnostic imaging, and research reagents. Through its subsidiary, Biotage, Inc.,

Dyax develops, manufactures and sells chromatography separations systems and products to pharmaceutical companies worldwide for drug discovery and purification. For more information on Dyax Corp., please visit its website at www.dyax.com.

#### **Dyax Disclaimer**

This press release contains forward-looking statements, including statements regarding our research and development program and collaboration with Debiopharm and the prospects for further clinical trials and commercialization of DX-890. Statements that are not historical facts are based on our current expectations, beliefs, assumptions, estimates, forecasts and projections about the industry and markets in which Dyax competes. The statements contained in this release are not guarantees of future performance and involve certain risks, uncertainties and assumptions, which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors that may affect the future of our research and development program and our collaboration with Debiopharm and the prospects for future clinical trials and commercialization of DX-890 include our dependence on the expertise, effort, priorities and contractual obligations of Debiopharm in the development, clinical trials, manufacture, marketing, sales and distribution of DX-890; the risk that DX-890 may not show therapeutic effect or an acceptable safety profile in clinical trials or could take a significantly longer time to gain regulatory approval than we expect or may never gain approval; the risk that DX-890 may not gain market acceptance; our ability to obtain and maintain intellectual property protection for our products and our technologies; the risk that others may develop technologies or products superior to our technologies or products; and other risk factors described or referred to in our most recent Annual Report on Form 10-K and our other periodic reports filed with the Securities and Exchange Commission. Dyax cautions investors not to place undue reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this release, and Dyax undertakes no obligations to update or revise these statements, except as may be required by law. Dyax specifically disclaims responsibility for the Debiopharm S.A. paragraph of information describing Debiopharm, which was provided by Debiopharm.

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