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Press Release

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New treatment a success for anaemia associated with chronic kidney disease

Basingstoke, UK – Thursday 14 September 2006

The first anti-anaemia treatment produced in a human cell line, DYNEPO[®] (epoetin delta), can effectively control anaemia in patients with chronic kidney disease (CKD*) according to two Phase III studies presented for the first time today.^{1,2}

Patients with kidney disease as a result of diabetes (diabetic nephropathy) were amongst the population effectively treated with this new treatment. The data were presented today at the 42nd Annual Meeting of the European Association for the Study of Diabetes (EASD).

DYNEPO is the first erythropoiesis-stimulating agent (ESA) to be produced by gene-activation technology in a human cell line and accordingly differs from all other available ESAs, which are all recombinant proteins produced in Chinese Hamster Ovary cells. The two large-scale Phase III studies have shown that treatment with DYNEPO can effectively maintain haemoglobin at target levels (10–12 g/dL) over a long period of time (up to 52 weeks) when administered by either intravenous or subcutaneous administration, with the data demonstrating overall efficacy when DYNEPO was used in various types of patients with anaemia associated with CKD – whether they require dialysis or not.

“Using a human cell line to produce DYNEPO through activation of the erythropoietin gene is a highly innovative method,” commented Dr. Jonathan Kwan, South West Thames Renal & Transplantation Unit, St. Helier Hospital, UK. “Also, because of the increasing trend for less frequent dosing intervals with ESAs, Shire is initiating a study to investigate a reduction in the dosing frequency of DYNEPO. The study will also evaluate the impact of treatment with DYNEPO on diabetic retinopathy which, together with diabetic nephropathy, is a serious complication in diabetes patients.”

* CKD is sometimes referred to as chronic renal failure (CRF).

Diabetic nephropathy is kidney disease that occurs as a result of diabetes and is the leading cause of kidney failure in the western world.³ Approximately two million people worldwide are undergoing treatment for end stage renal disease, of which approximately 77% are on dialysis.⁴ In patients with diabetic nephropathy, anaemia occurs at an earlier stage and is often more severe than in patients with CKD due to other causes.⁵ Anaemia is also implicated in the development of other microvascular complications of diabetes.⁶

Dr. Raymond Pratt, Vice President Global Medical Affairs, Shire said, “The studies underscore the emerging clinical interest in patients who are not only suffering from diabetes but also from the many complications, such as nephropathy, that it can cause. Shire is committed to meeting the needs of these patients, and to further investigate DYNEPO’s potential for distinct benefits in these patients.”

ABOUT DYNEPO

Erythropoietin is produced in the kidneys and stimulates the bone marrow to produce more red blood cells by promoting the development of stem cells into mature red blood cells. If the kidney starts to fail, patients require an increase in erythropoietin from a treatment such as DYNEPO in order to increase red blood cell production. Red blood cells (erythrocytes) contain haemoglobin and are vital for oxygen transportation around the body.

For further information please contact:

| | | |
|-----------------------------------|---|------------------|
| Media Shire | Jessica Mann | +44 1256 894 280 |
| Media PR agents for DYNEPO | Resolute Communications Lizzy Ray | +44 20 7357 8187 |
| Media PR agents for DYNEPO | Resolute Communications Dr Marilyn Ewan | +44 20 7357 8187 |

Notes to editors

SHIRE PLC

Shire's strategic goal is to become the leading specialty pharmaceutical company that focuses on meeting the needs of the specialist physician. Shire focuses its business on attention deficit and hyperactivity disorder (ADHD), human genetic therapies (HGT), gastrointestinal (GI) and renal diseases. The structure is sufficiently flexible to allow Shire to target new therapeutic areas to the extent opportunities arise through acquisitions. Shire believes that a carefully selected portfolio of products with a strategically aligned and relatively small-scale sales force will deliver strong results.

Shire's focused strategy is to develop and market products for specialty physicians. Shire's in-licensing and merger and acquisition efforts are focused on products in niche markets with strong intellectual property protection either in the US or Europe.

For further information on Shire, please visit the Company's website: www.shire.com.

References

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