Media release

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Basel, 19 October 2007

European licence for Roche HIV drug Viracept re-established by European Commission

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Roche ready to start re-supply of HIV medicine

Roche announced today that the European Commission (EC) has re-instated the Viracept marketing authorization following its suspension earlier this summer. Roche welcomes the news and fully intends to re-supply Viracept (nelfinavir) as soon as possible. The timing of the re-introduction will vary from country to country and it is likely to be a few months before it is fully available again to prescribers and patients.

"We are pleased that the marketing authorisation for Viracept has been re-instated in Europe." said William M. Burns, CEO of Roche's Pharmaceutical Division "Our teams have worked diligently in manufacturing and in close collaboration with the health authorities, health care providers, NGO treatment providers and patient groups on the recall with the full intention of re-supplying this medication."

Viracept's license was suspended in August this year following the discovery that some of the drug batches contained a substance called ethyl mesylate sulphonate (EMS).

About Viracept

Viracept (nelfinavir), a protease inhibitor is supplied by Roche outside the US, Canada and Japan. Viracept was first introduced by Roche in 1999.

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About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis

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and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, a market leader in virology and active in other major therapeutic areas such as autoimmune diseases, inflammation, metabolism and central nervous system. In 2006 sales by the Pharmaceuticals Division totaled 33.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.7 billion Swiss francs. Roche employs roughly 75,000 worldwide and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Roche's Diagnostics Division offers a uniquely broad product portfolio and supplies a wide array of innovative testing products and services to researchers, physicians, patients, hospitals and laboratories world-wide. For further information, please visit our website at www.roche.com.

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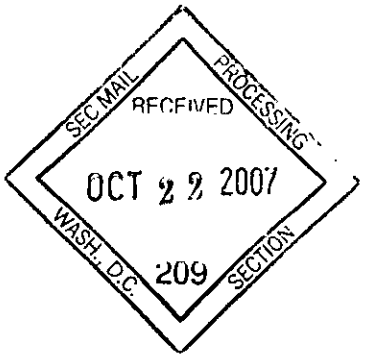

Basel, 19. October 2007

Pivotal Mircera study first to convert dialysis patients from frequent dosing directly to once every four weeks

MAXIMA findings in The Lancet affirm ability to maintain haemoglobin levels with less frequent dosing

A pivotal study published today in the Lancet has shown that dialysis patients can be effectively switched from frequently dosed anaemia drugs to an innovative new anaemia treatment, Mircera, that can be administered once a month[1].

The MAXIMA (Maintenance of Haemoglobin Excels in Intravenous Administration of C.E.R.A.) study is the first randomised, comparative study to investigate the direct conversion of dialysis patients with chronic kidney disease from treatment with erythropoiesis-stimulating agents (ESA) given one to three times a week to intravenous Mircera administered once every four weeks. The results demonstrated that Mircera maintains haemoglobin (Hb) concentrations within the target range as effectively as ESAs epoetin alfa or beta which must be given on a much more frequent basis.

"Our findings demonstrate that Mircera can be administered once every four weeks in haemodialysis patients without sacrificing haemoglobin stability", said Nathan Levin, Medical and Research Director, Renal Research Institute, New York, New York and the lead author of the publication. "We note in The Lancet that these results should be generalisable to the maintenance haemodialysis population and that we believe this drug should be an option to epoetin for simplified anaemia management".

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Simplified anaemia management a potential strategy to decrease rate of medication errors

The publication notes that conventional ESAs having short half-lives necessitating frequent administration to maintain stable Hb concentrations. Frequent administration, dose changes, and close monitoring of Hb concentrations complicate management of anaemia. The authors comment that "errors with medication errors occur at an unacceptably high rate of 45%. Extrapolation to about 246 000 haemodialysis patients in the USA, suggests that 111 000 dose errors could happen every month". The authors add that treatment with Mircera every four weeks would need only 13 doses per year, compared withy 52-156 doses with conventional epoetin and would therefore "allow fewer opportunities for error".

MAXIMA Study Details

The MAXIMA study randomised 673 adult patients with stable chronic renal anaemia on dialysis therapy and IV maintenance epoetin at 91 centres in eight countries. Most patients were from North America (USA – 68%; Canada – 11%) and Europe (21%). The study compared two administration intervals of IV Mircera (once every two weeks or once every four weeks) with continued IV epoetin treatment (one to three-times a week) in patients with chronic renal anaemia. After a run-in period, patients were randomly assigned to either of the Mircera arms or to continue epoetin alfa or beta at their current dose and administration interval. Patients randomized to Mircera received a starting dose based on the previous weekly dose of epoetin.

In contrast to previous studies in which dialysis patients were converted from IV epoetin using sequential increases in dosing intervals, most patients in MAXIMA were converted directly from a predominantly three-times-a-week regimen of epoetin (87% of patients) to IV Mircera administered once every four weeks.

The MAXIMA results showed:

- Minute changes in Hb levels throughout the duration of the study (mean changes from the baseline to the evaluation periods were –0.71, –0.25, and –0.75 g/L in the Mircera once every two weeks; Mircera once every four weeks and epoetin groups, respectively), illustrating that the primary efficacy parameter (mean change in Hb level between baseline and evaluation periods) was met.
- For the secondary analysis, the proportion of patients maintaining a mean Hb within ±10 g/L of baseline was 68%, 68%, and 67% in the Mircera once every two weeks and Mircera once every four weeks and epoetin groups, respectively.
- A similar incidence of adverse events across all treatment arms with the most frequent adverse events mild to moderate and had a distribution typical for this patient population.

About Mircera

Mircera, a continuous erythropoietin receptor activator, has a different activity at the receptor level involved in stimulating red blood cell production which more closely mimics the body's physiologic processes. This is believed to be instrumental in delivering predictable and stable haemoglobin levels with once-monthly maintenance dosing.

Mircera was approved in the EU in July and is the first ESA that offers a convenient dosing schedule of once every two weeks to correct anaemia in all CKD patients types not previously treated. Mircera is also the first ESA in the EU approved to directly convert all CKD patients types previously treated with any ESA to once-monthly dosing. The safety and efficacy of Mircera in other indications has not been established. Mircera has now been launched in Austria, Sweden, Germany and the UK, and was recently approved in Switzerland and Norway.

About CKD and anaemia

Globally more than 500 million people, approximately one in 10 of the general population, have some degree of chronic kidney disease (CKD)[2] .People with CKD experience a progressive deterioration in kidney function, often over a period of years until renal replacement therapy is needed. Patients whose kidneys are failing are unable to secrete erythropoietin, a protein that is produced by the kidneys and which stimulates the production of red blood cells in the bone marrow. ESAs are given to replace what the body can no longer produce. Renal anaemia is a common and significant complication of CKD and is responsible for a significant proportion of the distressing and disabling symptoms that affect the daily health and quality of life of patients with CKD. Anaemia is also instrumental in the development of potentially fatal cardiovascular disease in patients with CKD; the prevalence of cardiovascular illness in all populations with kidney disease (CKD not on dialysis, on dialysis and post-transplant) is approximately 35-40 %[3].

About Roche

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strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invests approximately 7 billion Swiss francs a year in R&D. Worldwide, the Group employs about 75,000 people. Additional information is available on the Internet at www.roche.com.

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[1] "Patients currently treated with an ESA can be converted to MIRCERA administered once a month as a single intravenous or subcutaneous injection" in the EU. See Summary of Product Characteristics (SMPC) @ www.emeaeuropa.eu for EU label.
[2] International Federation of Kidney Foundations. http://www.ifkf.net/resources.php.
[3] Levin A. The role of anaemia in the genesis of cardiac abnormalities in patients with chronic kidney disease. Nephrol Dial Transplant 2002; 17:207-210.

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