# *Media release*



Basel, 17 November 2003

## Roche's new anaemia drug CERA highly effective in dialysis patients with chronic anaemia

**First Phase II study with CERA shows potent and sustained stimulation of red blood cell formation with longer dosing intervals**

First results from a phase II clinical study with CERA (Continuous Erythropoiesis Receptor Activator) in dialysis patients with chronic renal anaemia have shown that Roche's innovative new chemical entity delivers potent and sustained stimulation of red blood cell formation at dosing intervals of up to once every three weeks.[1] CERA effectively increased haemoglobin at all studied doses, with increasing doses providing a more rapid response and extended dosing intervals not influencing the magnitude of the response. The results were presented during the annual meeting of the American Society of Nephrology (ASN) 14-17 November in San Diego, USA.
Phase III studies in renal patients are poised to begin in Europe and the USA early next year.

CERA is a Continuous Erythropoiesis Receptor Activator. Studies have shown that CERA has unique activity at the receptor site. It is postulated this is related to its repeated and rapid attachment and dissociation from the receptor involved in triggering erythropoiesis (red blood cell formation) together with an extended serum half life. This results in more potent stimulation of erythropoiesis, both in magnitude and duration, compared to standard epoetins.

"This first release of new data supports our belief that CERA will provide physicians and patients with better management options in anaemia," according to William M. Burns, Head of Roche's Pharmaceuticals Division. "This is an important step forward in achieving our goal of worldwide commercialization of CERA, allowing us access to the US market and further strengthening Roche's position in anaemia management."

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Commenting on the study results Professor Angel LM de Francisco from Hospital Universitario Valdecilla, Santander in Spain said, "This study demonstrates that CERA has potent erythropoietic activity in patients with chronic renal anaemia on dialysis. Higher doses resulted in faster response times and higher response rates. These results are encouraging for patients in the future as they may benefit from less frequent dosing intervals. For nephrologists this may also mean that they don't need to adjust the dose as frequently to achieve the desired target."

**About the study**

In a dose finding open-label, 12-week, multi-centre study in epoetin naïve dialysis patients (n=61) three dose levels (0.15 µg/kg, 0.30 µg/kg, 0.45 µg/kg) of CERA were tested in sequence, with three dosing intervals in each sequence.

Patients were randomised to receive CERA by subcutaneous injection as follows:

- Group 1 - 0.15 µg/kg once a week, 0.30 µg/kg every 2 weeks, and 0.45 µg/kg every 3 weeks
- Group 2 - 0.30 µg/kg once a week, 0.60 µg/kg every 2 weeks, and 0.90 µg/kg every 3 weeks
- Group 3 - 0.45 µg/kg once a week, 0.90 µg/kg every 2 weeks, and 1.35 µg/kg every 3 weeks

After 6 weeks individual dose adjustment was permitted and patients were followed for a total of 12 weeks. Significant and rapid haemoglobin (Hb) increases occurred in each dose group and at each dosing frequency. After 12 weeks of treatment over 70% of patients in the 0.15 µg/kg treatment group and 90% or more of patients in both 0.30 µg/kg and 0.45 µg/kg treatment groups had a consistent rise of at least 1 g/dl Hb. A faster response time was associated with increasing doses of CERA. In addition the haemoglobin increase was unrelated to dosing frequency. CERA demonstrated a favourable safety profile across all treatment groups.

Phase I/II clinical study results with CERA in the oncology setting will be presented next month at the American Society of Hematology Congress, to be held in San Diego, USA from 6-9 December.

**Roche in anaemia**

NeoRecormon (epoetin beta) is Roche's leading anaemia therapy for patients with kidney disease and cancer and it has been marketed for 12 years. In the renal segment, NeoRecormon is the European market leader. NeoRecormon also plays an increasingly important role in the management of anemia in cancer patients. CERA is the most recent demonstration of Roche's commitment to anaemia management.

## About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. Roche is number one in the global diagnostics market, the leading supplier of pharmaceuticals for cancer and a leader in virology and transplantation. As a supplier of products and services for the prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche employs roughly 65,000 people in 150 countries. The Group has alliances and research and development agreements with numerous partners, including majority ownership interests in Genentech and Chugai.



**References:**

1. Angel LM de Francisco. Subcutaneous CERA (Continuous Erythropoiesis Receptor Activator) has potent erythropoietic activity in dialysis patients with chronic renal failure; an exploratory multiple-dose study. Oral presentation; 15th November 2003: American Society of Nephrology, San Diego, USA.