

# **EXHIBIT 1**

Roche - Media News



Media News

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**Mircera: first drug to correct anaemia in all chronic kidney disease patients with a simple twice-monthly dosing schedule**

Results from two Roche studies show for the first time that chronic kidney disease patients on dialysis as well as those not on dialysis who need correction of renal anaemia, can be successfully treated with Mircera on a simple twice monthly dosing schedule – an option that does not exist today. Mircera was shown to be as effective as existing agents in correcting renal anaemia while reducing the dosing frequency 2 to 6-fold of these drugs. Two phase III trials demonstrating these findings were presented at the 39th annual meeting of the American Society of Nephrology in San Diego, USA.

"There is no doubt that Mircera is very effective at correcting anaemia," said Dr. Iain Macdougall, Consultant Nephrologist and Honorary Senior Lecturer at King's College Hospital in London and an investigator in the ARCTOS trial. "We were pleased to see a smooth rise in, and stable control of, haemoglobin at these initial dosing intervals of twice a month. It is important with new patients being treated for the first time to feel confident in carefully managing their rise in haemoglobin."

Mircera the first and only Continuous Erythropoietin Receptor Activator (C.E.R.A.), is a new drug under development for the treatment of anaemia in patients with CKD. Roche filed applications with regulatory authorities in the European Union and the United States in April this year seeking approval for use of the treatment in anaemia associated with CKD in patients on dialysis and not on dialysis.

**About the ARCTOS and AMICUS studies**

The primary objective of these two correction studies, ARCTOS and AMICUS, was to examine the effectiveness of intravenous (IV) and subcutaneous (SC) Mircera at extended administration intervals in correcting anaemia and maintaining Hb levels in treatment-naive patients with CKD either on dialysis or not. The studies used epoetin alfa/beta or darbepoetin alfa as comparator agents in a non-inferiority design<sup>1</sup>.

In the first study, ARCTOS (Administration of C.E.R.A. in CKD Patients to Treat Anaemia with a Twice Monthly Schedule), 324 patients with CKD who were not on dialysis were randomized to either Mircera once every two weeks or darbepoetin alfa once a week subcutaneously. The response rate was 97.5% for Mircera and 96.3% for darbepoetin. After 28 weeks, patients who responded to Mircera were randomized to continue treatment twice a month or monthly with the same dose; patients on darbepoetin remained on once-weekly treatment. In a

post-hoc analysis, only 12.4% of patients on Mircerca had one Hb value greater than 13 g/dL during the first 8 weeks while 33.5% of patients on darbepoetin alfa exceeded this upper limit.

"Effective elevation and predictable control of haemoglobin are key to managing renal anaemia, improving physical functioning and reducing the risk of complications," said Robert Provenzano, Chief, Division of Nephrology, Hypertension & Transplantation, St. John Hospital & Medical Center in Detroit, Michigan and an investigator with one of the US-based clinical trial sites for ARCTOS. "These results show Mircerca may provide doctors with a way to manage anaemia with less frequent dosing."

The second study, AMICUS (C.E.R.A. AdMinistered Intravenously for Anaemia Correction and SUSTained Maintenance in Dialysis), examined intravenous Mircerca once every two weeks against the controls, epoetin alfa or epoetin beta 1-3x/wk, in 181 dialysis patients. 93.3% of patients on Mircerca achieved target Hb levels versus 91.3% for epoetin alfa or beta, indicating Mircerca is effective in maintaining Hb levels with a single dose every two weeks.

"These findings demonstrate Mircerca's clear ability to effectively and safely correct anaemia in patients on dialysis along with offering a convenience for patients and medical staff with extended twice monthly dosing intervals," said Marian Klinger, MD, Medical University, Wroclaw, Poland and an investigator in the AMICUS study.

### **About Renal Anaemia**

Renal anaemia is a common and debilitating complication of CKD that's characterized by a low concentration of haemoglobin (Hb) in the blood. Inadequate Hb levels deprive the body's tissues of oxygen and can lead to serious cardiovascular complications and even death if left untreated. Treatment guidelines recommend specific ranges that they suggest doctors target – achieving an Hb  $\geq$  11 g/dL and maintaining Hb levels in the optimal range as excessive Hb correction is not associated with additional benefit and has been associated with increased risk. Most CKD patients receive chronic anti-anaemia treatment as often as 52-156 times a year because existing agents for renal anaemia are short-acting, requiring more frequent administration to keep Hb levels within guideline ranges. Today's results, presented at the 39th Annual Meeting of the American Society of Nephrology, indicate Mircerca can successfully correct Hb with twice monthly dosing.

### **About the phase III clinical trial program**

The Mircerca phase III clinical program was the largest clinical development program ever conducted for the treatment of renal anaemia. The program consisted of two initiation/correction and four conversion/maintenance studies of both IV and SC Mircerca at extended administration intervals. Initial findings from the phase III 'maintenance studies,' were presented at the European Renal Association-European Dialysis and Transplant Association congress in July 2006. These results showed that for the first time, patients with CKD on dialysis treated with short-acting and frequently administered epoetin anti-anaemia drugs can be successfully and directly switched to a once-monthly treatment, resulting in stable Hb levels.

**About Mircera**

Roche's innovative investigational anti-anaemia agent is the first Continuous Erythropoietin Receptor Activator (C.E.R.A.), which is a new class of drugs. Its activity at the receptor sites involved in stimulating red blood cell production is different from that observed with traditional epoetin drugs. The distinct molecular interaction of Mircera is believed to play an important role in providing targeted, stable and sustained control of anaemia.

**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 a supplier of innovative products and services for the early detection, 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 is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2005 sales by the Pharmaceuticals Division totalled 27.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.2 billion Swiss francs. Roche employs roughly 70,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet ([www.roche.com](http://www.roche.com)).

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**Further information**

- [Anemia treatment](#)
- [Correction of anemia](#)

1 Non-inferiority studies are required to gain registration for a medicine when treatments already exist to manage the condition in question as placebo controlled studies are no longer ethical. In this situation, regulatory authorities ask for studies showing the new medicine to be at least as effective to existing agents with a similar safety profile.

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