



## **KURO MEETS PRIMARY ENDPOINT IN A PHASE IIB TRIAL OF KUR-113 IN PATIENTS WITH OPEN TIBIAL SHAFT FRACTURES**

**Second successful Phase Iib study in bone repair indications highlights the potential of Kuros "TG Hook" Technology**

**Zurich, Switzerland, 26 April 2011** - Kuros Biosurgery AG, a biotechnology company focused on the development of novel biomaterials and bioactive-biomaterial combination products for trauma, wound and spinal indications, announced today that KUR-113 (Viz.I-040202) met the primary efficacy endpoint in a 200 patient Phase Iib clinical trial designed to assess its efficacy and safety in open tibial shaft fracture patients. The primary endpoint of the study is the proportion of patients healed at 6 months after surgery, comparing KUR-113 in combination with standard of care (SOC) to SOC alone. The use of KUR-113 is designed to improve fracture union and thus reduce the time needed to achieve bone healing as well as the incidence of secondary interventions.

The Phase Iib study is a randomized, controlled, open-label (dose-blinded) dose finding study of the safety and efficacy of KUR-113 in the treatment of patients with acute open tibial shaft fractures. A total of 200 patients were randomized and treated in 31 centers across Europe. Three doses of KUR-113 in combination with SOC were compared with SOC alone.

In the Intent-to-Treat (ITT) population the healing rate at 6 months after surgery, as assessed by the investigators using radiographic and clinical criteria, was 65% for patients treated with SOC alone versus 76%, 80%, and 69% for the 0.133, 0.4 and 1.0 mg/ml KUR-113 groups respectively. In the Per-Protocol (PP) population, the healing rates were 63% in the SOC alone group versus 74%, 83%, and 75% for the 0.133, 0.4 and 1.0 mg/ml KUR-113 groups respectively. For both analyses the 0.4 mg/ml group had significantly better healing than SOC alone group. To date there are no indications of any safety issues. Analysis of the secondary endpoints is ongoing.

KUR-113 utilizes Kuros' "TG-hook" technology for binding proprietary biologics into a fibrin sealant. The product candidate is composed of a variant of parathyroid hormone (vPTH) and fibrin sealant and is applied directly to the fracture site in the form of a paste. KUR-113 has been designed to deliver vPTH locally at the fracture site and to maintain this via the slow controlled release of vPTH over time from the fibrin matrix. The fibrin matrix also plays a further important role in the bone healing process by providing a physical scaffold for cell ingrowth.

Dr. Virginia Jamieson, Chief Medical Officer of Kuros, commented: "We are extremely pleased to have met the primary endpoint of this study. Demonstrating a significant improvement in the clinically assessed healing rate in patients with open tibial shaft fractures, using a very challenging endpoint, is a great achievement for a Phase II trial with this number of patients".

Didier Cowling, Chief Executive Officer of Kuros, commented: "We have now tested our fibrin-vPTH combination product technology in large Phase II studies in two different indications. Both studies have met their primary endpoint generating further evidence of the efficacy of our TG-hook technology in general and more specifically of our bone regeneration product candidates. Kuros believes that the efficacy and the ease of application of these

product candidates means that they could be of significant potential benefit to both patients and clinicians”.

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### **About tibial shaft fractures**

The tibia is the major bone between the knee and ankle, often referred to as the shin bone. Fractures of the tibial shaft are the most common long-bone fractures treated by an orthopedic surgeon. They are generally regarded as difficult to treat due to the risk of non-union and other secondary complications. Improving the healing rate and reducing the incidence of secondary complications is therefore of great importance to these patients.

### **About Kuros**

[www.kuros.ch](http://www.kuros.ch)

Kuros is a biotechnology company that is focused on the development of novel biomaterials and bioactive-biomaterial combination products for trauma, wound and spinal indications.

Kuros has two biomaterial technology platforms, one based on fibrin sealants and the other based on its own proprietary synthetic technology that can mimic fibrin in many of its attributes. These materials can be used alone or in combination with biologically active molecules.

The synthetic technology is tailorable and allows generation of products that are delivered as liquids or gels but polymerise, in or on living tissues, to form materials with different physical properties. For example, Kuros' synthetic technology can be utilized to develop products ranging from an elastic degradable dural sealant to a strong and non-degradable bone cement.

Kuros' combination products are designed to mimic the body's natural healing process. The products consist of fusion proteins or naturally occurring bioactive factors, covalently incorporated into fibrin or synthetic matrices. The incorporation of the biologically active molecules into the injectable matrices aims to maximize their activity by retention at the site of action. Kuros products are designed to combine ease of application with localized delivery. Kuros has a number of methodologies to achieve the desired retention and release profiles of the biologically active molecules.

Kuros' has a diverse pipeline of product candidates with its most advanced product candidates being in trauma and wound care.

Since its creation, Kuros has raised over \$100 million. The company is located in Zurich, Switzerland.

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