Bone Therapeutics

First trial of its kind to investigate bone cell therapy in severe treatment-resistant osteoporosis

Gosselies, Belgium, 16 April 2013 - BONE THERAPEUTICS, the leading international biopharmaceutical company focused on innovative cell therapy products for the treatment of bone diseases, announces today that its partner, the Rheumatology Department of Erasme University Hospital (Brussels, Belgium), has initiated a Phase IIa trial with its lead bone cell therapy product PREOB® for the treatment of severe osteoporosis patients who do not respond to pharmacological treatment.

PREOB® is Bone Therapeutics' first-in-class autologous osteoblastic (bone forming) cell therapy product. Due to its unique mechanism of action, PREOB® could have a significant role to play in the treatment of severe osteoporosis, where the majority of current treatments do not provide bone forming/anabolic activity as their mechanism of action and where over 40% of patients under treatment are still losing bone mass and fracture PREOB® is currently in two pivotal Phase III trials for the treatment of osteonecrosis and non-union fractures.

This Phase IIa study is a six month open-label trial enrolling 20 patients with severe osteoporosis who do not respond to anti-osteoporotic treatment. PREOB® will be administered via a single intravenous infusion, and the primary endpoints of the trial will be cell body distribution and bone markers. The trial is the first of its kind to be initiated globally and will be run at the Erasme University Hospital (Free University of Brussels (ULB), Belgium).

Bone Therapeutics has been granted from the Free University of Brussels an exclusive worldwide license for PREOB® currently in Phase III clinical trials. Bone Therapeutics was founded in 2006 based on the pioneering works carried out at Erasme University Hospital-ULB, Brussels, Belgium. The Company still maintains close collaborations with scientific experts from various universities such as Prof. Gangji who is now head of the Rheumatology Department of the ULB Erasme Hospital.

Osteoporosis is a disease causing bone fragility and weakness and affects over 200 million people worldwide. Due to aging populations and growing awareness of the disease, the global market for osteoporosis therapeutics is expected to reach $8.8 billion in 2015.

Enrico Bastianelli, Chief Executive Officer of Bone Therapeutics, commented: "We are delighted to be expanding the potential of our lead product PREOB®

to osteoporosis, a large disease area with significant unmet need, under the existing agreement that we have with the Free University of Brussels."

Valérie Gangji, Head of Rheumatology, Erasme University Hospital commented: "We are very excited to be investigating the potential of PREOB®

in treatment-resistant osteoporosis, where PREOB®

's unique mechanism of action could have a real impact on patients. A new treatment such as PREOB®

that could reduce the risk of fracture and form new bone could significantly improve the quality of life of these osteoporotic patients."

About Bone Therapeutics

Bone Therapeutics is a leading international biopharmaceutical company focused on innovative cell therapy products for the treatment of bone diseases. Utilizing the Company's unique knowledge of the bone/joint physiology and long-standing expertise in cell therapy and cell transplantation, Bone Therapeutics has created a fully integrated business with an advanced product pipeline comprising novel bone cell products, tailored in-house production methods, and minimally invasive treatment techniques.

Bone Therapeutics' lead product, PREOB®, is an autologous bone cell product, currently in Phase III clinical trials for the treatment of osteonecrosis and non-union fractures. Bone Therapeutics is also developing an allogeneic bone cell therapy product, ALLOB®, which is expected to enter the clinic in 2013, and MXB, a combined cell-matrix product for the treatment of large bone defects, currently in preclinical development. All of Bone Therapeutics'

cell therapy products are manufactured to the highest GMP standards and protected by a rich IP estate.

The bone disease and reconstruction market is one of the largest healthcare markets in the world, with more than 4 million procedures requiring bone grafts performed annually in Europe and the USA alone. Bone Therapeutics is operating in areas where demand for new products is high and competition is low. Founded in 2006, Bone Therapeutics is privately held and headquartered in Gosselies (south of Brussels), Belgium. Further information is available at: w ww.bonetherapeutics.com