



Kuros Biosciences' KUR-112 Receives Rare Pediatric Disease Designation

October 20, 2016

Kuros Biosciences announced today that the U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease Designation to KUR-112, an investigational product candidate for the treatment of Solitary Bone Cysts (SBC).

Schlieren (Zurich), Switzerland, October 20, 2016

SBCs are non-malignant fluid-filled cavities found primarily in the long bones of children. In severe cases, bone cysts may lead to pathological fractures. Currently used methods for the management of SBCs (bone grafting, intra-lesion corticosteroid injections and bone marrow injections) require multiple applications and show only limited efficacy. Hence, there is a clear need for a simple effective treatment of SBCs. It is estimated that there is an incidence of less than 1 case per 10,000 of the general population per year in Europe and the US, and the vast majority of these are pediatric.

KUR-112 is a parathyroid hormone-fibrin-based product. It is intended to be applied as a single percutaneous injection into SBCs and could therefore become a simpler, minimally invasive treatment for this condition.

Under the FDA's Rare Pediatric Disease Priority Review Voucher program, a sponsor who receives approval of a new drug application or biologics license application for a rare pediatric disease is eligible for a voucher. This voucher can be redeemed to obtain priority review for any subsequent marketing application and may be sold or transferred to other companies or organizations. This voucher program is due to expire on 31 December 2016 and it is not certain the program will be renewed.

KUR-112 has already obtained Orphan Drug Designation by the FDA and the European Medicines Agency (EMA), which entitles the sponsor of the drug to receive assistance in the development process, exemption from application fees and several years of marketing exclusivity following approval. The sponsor may also be eligible for grant funding and significant tax credits.

Didier Cowling, Chief Executive Officer of Kuros, commented: "We are very pleased to have received this Rare Pediatric Disease Designation, which builds on the Orphan Drug Designation granted to KUR-112 by the FDA and the EMA previously. We will now carefully consider development options for KUR-112."

About Kuros Biosciences Ltd

Kuros Biosciences is focused on the development of innovative products for tissue repair and regeneration and is located in Schlieren (Zurich), Switzerland. The Company is listed according to the International Financial Reporting Standard on the SIX Swiss Exchange under the symbol KURN. Visit www.kuros.ch for additional information on Kuros, its science and product pipeline.

Forward Looking Statements

This media release contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. You are urged to consider statements that include the words "will" or "expect" or the negative of those words or other similar words to be uncertain and forward-looking. Factors that may cause actual results to differ materially from any future results expressed or implied by any forward-looking statements include scientific, business, economic and financial factors. Against the background of these uncertainties, readers should not rely on forward-looking statements. The Company assumes no responsibility for updating forward-looking statements or adapting them to future events or developments.

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