Keryx Biopharmaceuticals Announces Positive Top-Line Results from Phase 3 Study of Ferric Citrate (Zerenex (TM)) in Japan by Partner, Japan Tobacco and Torii Pharmaceutical

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NEW YORK, April 23, 2012 /PRNewswire via COMTEX/ --Keryx Biopharmaceuticals, Inc. (Nasdaq: KERX), announced today that its Japanese partner, Japan Tobacco Inc. (JT) and Torii Pharmaceutical Co., Ltd. (Torii), has announced positive top-line results from a Phase 3 study of ferric citrate in Japan for the treatment of hyperphosphatemia in end-stage renal disease patients on hemodialysis. This study is part of an ongoing Phase 3 program for ferric citrate in Japan for the treatment of hyperphosphatemia.

The Phase 3 study, conducted in Japan, was an open-label, randomized study evaluating the efficacy and safety of ferric citrate against an active control, sevelamer hydrochloride, over 12 weeks in hemodialysis patients with hyperphosphatemia. In the top-line results, which evaluated the change of serum phosphorus from baseline, the primary endpoint of efficacy met non-inferiority to sevelamer hydrochloride. Furthermore, there were no clinically significant findings on safety and tolerability of ferric citrate within the treatment period.

JT/Torii stated that it is aiming to submit the marketing application for ferric citrate in Japan in the fiscal year ending March 31, 2013.

Ron Bentsur, Chief Executive Officer of Keryx, said, "We congratulate our partner, JT/Torii, on their successful Phase 3 study and we are excited by their progress. We are also encouraged about our partner's plans to file their marketing application in Japan within less than a year, similar to our expected timelines for the U.S. NDA and European MAA filings." Mr. Bentsur added, "We are enthusiastic about Zerenex's potential differentiated product profile and its prospects for becoming an important part of the treatment of hyperphosphatemia in dialysis patients worldwide."

Zerenex(TM) (ferric citrate), a ferric iron-based phosphate binder, is also in a Phase 3 clinical program in the United States for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease on dialysis, which is being conducted pursuant to a Special Protocol Assessment agreement with the FDA.

Keryx holds a worldwide license (except for certain Asian Pacific countries) to Zerenex from Panion & BF Biotech, Inc.

Sublicense Agreement with Japan Tobacco & Torii Pharmaceutical

In September 2007, Keryx sublicensed to JT/Torii the exclusive rights for the development and commercialization of its hyperphosphatemia drug, Zerenex (ferric citrate), in Japan. The licensing arrangement calls for JT/Torii to pay to Keryx up to $100 million in up-front license fees and payments upon the achievement of specified milestones, of which $28 million has been received by Keryx to date. In addition, upon commercialization, JT/Torii will make royalty payments to Keryx on net sales of the drug in Japan. JT/Torii are responsible for all development and commercialization costs in Japan.

About Keryx Biopharmaceuticals, Inc.

Keryx Biopharmaceuticals is focused on the acquisition, development and commercialization of medically important pharmaceutical products for the treatment of renal disease and cancer. Keryx is developing Zerenex (ferric citrate), an oral, ferric iron-based compound that has the capacity to bind to phosphate and form non-absorbable complexes. The Phase 3 clinical program of Zerenex for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease is being conducted pursuant to a Special Protocol Assessment (SPA) agreement with the FDA. Keryx is also developing KRX-0401 (perifosine), which is in Phase 3 clinical development for multiple myeloma. Keryx is headquartered in New York City.

Cautionary Statement

Some of the statements included in this press release, particularly those anticipating future clinical trials and business prospects for Zerenex(TM) (ferric citrate) may be forward-looking statements that involve a number of risks and uncertainties. For those

statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Among the factors that could cause our actual results to differ materially are the following: our ability, and our Japanese partner's ability, to successfully and cost-effectively complete clinical trials for Zerenex (ferric citrate); the risk that the data (both safety and efficacy) from the ongoing Phase 3 trials will not coincide with the data analyses from previous clinical trials reported by the Company; our ability to meet anticipated development timelines for Zerenex due to clinical trial results, manufacturing capabilities or other factors; if we determine that all trials of KRX-0401 (perifosine) should be terminated, our ability to successfully adjust our strategy and reduce our operating expenses relating to KRX-0401 clinical trials in order to properly support the trials of Zerenex; and other risk factors identified from time to time in our reports filed with the Securities and Exchange Commission. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. This press release and prior releases are available at http://www.keryx.com. The information found on our website is not incorporated by reference into this press release and is included for reference purposes only.

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