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Raptor Pharmaceutical Announces FDA Acceptance of New Drug Application for RP103 for the Potential Treatment of Nephropathic Cystinosis

Raptor Focused on a Robust US and EU Launch

NOVATO, Calif., June 13, 2012 (GLOBE NEWSWIRE) -- Raptor Pharmaceutical Corp. ("Raptor" or the "Company") (Nasdaq:RPTP) today announced that the U.S. Food and Drug Administration ("FDA") has accepted for filing the Company's New Drug Application ("NDA") for its investigational drug candidate, Cysteamine Bitartrate Delayed-release Capsules ("RP103"), for the potential treatment of nephropathic cystinosis. The FDA has granted Standard Review designation for RP103.

Previously, Raptor announced that the European Medicines Agency ("EMA") had validated its Marketing Authorization Application ("MAA") for RP103 for the potential treatment of nephropathic cystinosis. Raptor's MAA is under review by the EMA, and the Company expects a decision in the first half of 2013.

"We are very pleased that the FDA has accepted our NDA," said Christopher M. Starr, Ph.D., Raptor's Chief Executive Officer. "We are focused and working hard to build our internal and external infrastructure in order to support a robust commercial launch so that Raptor can quickly provide this important therapeutic to the cystinosis community in the US and the European Union."

The NDA submission for marketing approval includes previously announced data from Raptor's Phase 3 cystinosis clinical trial of RP103. As reported, RP103 met the clinical trial's sole primary endpoint and there were no unexpected serious safety concerns attributable to RP103 experienced by patients in the trial. The clinical trial was conducted at three clinical sites in the U.S. and five clinical sites in Europe.

About Nephropathic Cystinosis

Nephropathic cystinosis, an orphan disease, is estimated to effect a population of 2,000 patients worldwide, including 500 patients in the U.S. and 800 patients in Europe. Cystinosis patients have inherited a defective cystine transporter gene which results in body-wide cellular toxicity resulting from the abnormal buildup of the amino acid cystine in the lysosomes. Cystinosis is usually diagnosed in the first year of life and requires lifelong therapy. Cystine crystals accumulate in various tissues and organs, including the kidneys, brain, liver, thyroid, pancreas, muscles and eyes. Left untreated, the disease is fatal by the first decade of life. RP103 reduces cellular toxicity by continuously removing cystine from the lysosome.

About Cysteamine and RP103

RP103 is Raptor's proprietary delayed release oral medication designed to potentially treat the underlying metabolic cause of cystinosis. RP103 is an enteric coated, microbead formulation of cysteamine bitartrate that has been formulated to be sprinkled onto food for administration to patients too young to take oral capsules.

In December 2007, Raptor obtained an exclusive, worldwide license from the University of California, San Diego for the development of RP103 for nephropathic cystinosis and for cysteamine for other potential indications including Huntington's Disease currently in a Phase 2/3 clinical trial in France and non-alcoholic steatohepatitis ("NASH") currently in a Phase 2b clinical trial in the U.S. Raptor has been granted orphan product designation for RP103 for the potential treatment of nephropathic cystinosis by the EMA and FDA and for the potential treatment of Huntington's Disease by the FDA.

About Raptor Pharmaceutical Corp.

Raptor Pharmaceutical Corp. (Nasdaq:RPTP) ("Raptor") seeks to research, produce, and deliver medicines that improve life for patients with severe, rare disorders. Raptor currently has product candidates in clinical development designed to potentially treat nephropathic cystinosis, Non-alcoholic Steatohepatitis ("NASH"), Huntington's Disease ("HD"), aldehyde dehydrogenase deficiency ("ALDH2"), and thrombotic disorder.

Raptor's preclinical programs are based upon bioengineered novel drug candidates and drug-targeting platforms derived from the human receptor-associated protein and related proteins that are designed to target cancer and infectious diseases.

For additional information, please visit www.raptorpharma.com.

The Raptor Pharmaceutical Corp. logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=7180

FORWARD LOOKING STATEMENTS

This document contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements relate to future events or our future results of operation or future financial performance, including, but not limited to the following statements: that Raptor will receive marketing approval of RP103 for the potential treatment of cystinosis in the U.S. or the European Union; that Raptor will receive a decision from the EMA in the first half of 2013; that Raptor will be able to support a robust commercial launch of RP103 for the potential treatment of cystinosis in the US or European Union, if at all; and that Raptor will be able to successfully develop RP103 or any of its other product candidates. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, which may cause the Company's actual results to be materially different from these forward-looking statements. Factors which may significantly change or prevent the Company's forward looking statements from fruition include: that Raptor may be unsuccessful in developing any products or acquiring products; that Raptor's technology may not be validated as it progresses further and its methods may not be accepted by the scientific community; that Raptor is unable to retain or attract key employees whose knowledge is essential to the development of its products; that unforeseen scientific difficulties develop with the Company's process; that Raptor's patents are not sufficient to protect essential aspects of its technology; that competitors may invent better technology; that Raptor's products may not work as well as hoped or worse, that the Company's products may harm recipients; and that Raptor may not be able to raise sufficient funds for development or working capital. As well, Raptor's products may never develop into useful products and even if they do, they may not be approved for sale to the public. Raptor cautions readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they were made. Certain of these risks, uncertainties, and other factors are described in greater detail in the Company's filings from time to time with the Securities and Exchange Commission (the "SEC"), which Raptor strongly urges you to read and consider, including: Raptor's annual report on Form 10-K, as amended by Form10-K/A, filed with the SEC on November 11, 2011 and December 19, 2011, respectively; and Raptor's quarterly report on Form 10-Q filed with the SEC on April 9, 2012; all of which are available free of charge on the SEC's web site at http://www.sec.gov. Subsequent written and oral forward-looking statements attributable to Raptor or to persons acting on its behalf are expressly qualified in their entirety by the cautionary statements set forth in Raptor's reports filed with the SEC. Raptor expressly disclaims any intent or obligation to update any forward-looking statements.

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