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PTC Therapeutics Announces Workforce Reduction as Part of Operating Expense Management Plan

SOUTH PLAINFIELD, N.J., March 23, 2016 /PRNewswire/ -- PTC Therapeutics, Inc. (NASDAQ: PTCT) today announced that the company is reducing its workforce by approximately 18%, which will primarily affect employees and contractors in the U.S. This reduction is part of PTC's program intended to optimally manage operating expenses following its recent setback related to the Refuse to File letter received from the U.S. Food and Drug Administration (FDA) for Translarna™ (ataluren) for the treatment of nonsense mutation Duchenne muscular dystrophy (nmDMD). PTC remains focused on the global development of Translarna and commercialization outside of the U.S. for nmDMD. In parallel, PTC intends to work with the FDA to determine the best path forward to bring Translarna to patients in the U.S.

"I would like to express my sincere appreciation to those employees affected by today's announcement," said Stuart W. Peltz, Ph.D., Chief Executive Officer, PTC Therapeutics, Inc. "While it is very difficult to part with this talented group of colleagues, it was a necessary step to better align our resources and enable us to continue our mission of bringing treatments to patients suffering from rare and neglected disorders."

PTC plans to complete this workforce reduction by June 30, 2016 and expects to incur related employee severance and benefit costs of approximately \$2.5 million.

About Translarna™ (ataluren)

Translarna, discovered and developed by PTC Therapeutics, Inc., is a protein restoration therapy designed to enable the formation of a functioning protein in patients with genetic disorders caused by a nonsense mutation. A nonsense mutation is an alteration in the genetic code that prematurely halts the synthesis of an essential protein. The resulting disorder is determined by which protein cannot be expressed in its entirety and is no longer functional, such as dystrophin in Duchenne muscular dystrophy. Translarna is licensed in the European Economic Area (EEA) for the treatment of nonsense mutation Duchenne muscular dystrophy in ambulatory patients aged five years and older. Translarna is an investigational new drug in the United States. The development of Translarna has been supported by grants from Cystic Fibrosis Foundation Therapeutics Inc. (the nonprofit affiliate of the Cystic Fibrosis Foundation); Muscular Dystrophy Association; FDA's Office of Orphan Products Development; National Center for Research Resources; National Heart, Lung, and Blood Institute; and Parent Project Muscular Dystrophy.

About PTC Therapeutics

PTC is a global biopharmaceutical company focused on the discovery, development and commercialization of orally administered, proprietary small molecule drugs targeting an area of RNA biology we refer to as post-transcriptional control. Post-transcriptional control processes are the regulatory events that occur in cells during and after a messenger RNA, or mRNA, molecule is copied from DNA through the transcription process. PTC's internally discovered pipeline addresses multiple therapeutic areas, including rare disorders and oncology. PTC has discovered all of its compounds currently under development using its proprietary technologies. PTC plans to continue to develop these compounds both on its own and through selective collaboration arrangements with leading pharmaceutical and biotechnology companies. For more information on the company, please visit our website www.ptcbio.com.

For More Information:

Investors:

Jane Baj
+1 (908) 912-9167
jbaj@ptcbio.com

Media:

Justine O'Malley
+1 (908) 912-9551
jomalley@ptcbio.com

Forward Looking Statements:

All statements, other than those of historical fact, contained in this press release, are forward-looking statements, including statements regarding the extent, timing and financial aspects of the reduction in workforce; PTC's strategy, future operations, future financial position, future revenues or projected costs, including PTC's ability to manage its operating expenses; the objectives of management; PTC's ability to maintain its current marketing authorizations or its ability to make Translarna available pursuant to certain early access programs and PTC's ability to obtain and maintain additional marketing authorizations or access under additional early access programs; PTC's ability to work with the FDA to resolve the matters set forth in the Refuse to File letter PTC received in connection with its new drug application for Translarna for the treatment of nmDMD; the price of Translarna for the treatment of nmDMD in territories where PTC is or may be authorized to market Translarna; the clinical utility and potential advantages of Translarna; the timing and scope of PTC's commercial and early access program launches; the rate and degree of market acceptance of Translarna; PTC's estimates regarding the potential market opportunity for Translarna, including the size of eligible patient populations and PTC's ability to identify such patients; the timing, results and conduct of PTC's clinical trials and studies of Translarna for the treatment of nonsense mutation cystic fibrosis and other indications; and the future expectations, plans and prospects for PTC. Other forward-looking statements may be identified by the words "plan," "guidance," "anticipate," "believe," "estimate," "expect," "intend," "may," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions.

PTC's actual results, performance or achievements could differ materially from those expressed or implied by forward-looking statements it makes as a result of a variety of risks and uncertainties, including those related to: the timing of and actual expenses incurred in connection with the reduction in workforce, which may be in different periods and may be materially higher than we estimate; the savings that may result from the reduction in workforce, which may be materially less than we expect; the timing and outcome of future interactions PTC has with the FDA with respect to Translarna for the treatment of nmDMD, including whether PTC is required to perform additional clinical and non-clinical trials at significant cost and whether such trials, if successful, may enable FDA review of a NDA submission; whether the FDA, the European Medicines Agency (EMA) or other regulators agree with PTC's interpretation of the results of ACT DMD or PTC's other clinical trials; the outcome of pricing and reimbursement negotiations in those territories in which PTC is authorized to sell Translarna; whether patients and healthcare professionals may be able to access Translarna through alternative means if pricing and reimbursement negotiations in the applicable territory do not have a positive outcome, including whether Translarna may be accessed through a reimbursed importation pathway provided under German law and whether such pathway will minimize any access issues for German patients while maintaining a sustainable price; expectations for regulatory approvals, including PTC's ability to make regulatory submissions in a timely manner (or at all), the period during which the outcome of regulatory reviews will become available, adverse decisions by regulatory authorities, other delay or deceleration of the regulatory process, and PTC's ability to meet existing or future regulatory standards with respect to Translarna; the scope of regulatory approvals or authorizations for Translarna (if any), including labeling and other matters that could affect the availability or commercial potential of Translarna; PTC's ability to maintain the marketing authorization of Translarna for the treatment of nmDMD in the European Economic Area (EEA), which is subject to annual review and renewal by the EMA following its reassessment of the risk benefit balance of the authorization; PTC's ability to obtain full marketing authorization in the EEA or obtain or maintain marketing authorizations in territories outside the EEA; PTC's ability to maintain its current ability to make Translarna available pursuant to certain early access programs and its ability to access additional early access programs in other territories; PTC's ability to commercialize and commercially manufacture Translarna in general and specifically as a treatment for nmDMD; PTC's ability to fulfill any additional obligations, including with respect to further trials or studies relating to cost-effectiveness, obtaining licenses or satisfying requirements for labor and business practices, in the territories in which it may obtain regulatory approval, including the United States, EEA and other territories; the initiation, conduct and availability of data from clinical trials and studies; PTC's scientific approach and general development progress; the eligible patient base and commercial potential of Translarna and PTC's other product candidates; the outcome of ongoing or future clinical trials or studies; PTC's ability to establish and maintain arrangements with manufacturers, suppliers, distributors and production and collaboration partners on favorable terms; the sufficiency of PTC's cash resources and PTC's ability to obtain adequate financing in the future for PTC's foreseeable and unforeseeable operating expenses and capital expenditures; and the factors discussed in the "Risk Factors" section of PTC's most recent Annual Report on Form 10-K as well as any updates to these risk factors filed from time to time in PTC's other filings with the SEC. You are urged to carefully consider all such factors.

As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that Translarna will receive full regulatory approval in any territory or maintain its current marketing authorization in the EEA, or prove to be commercially successful in general, or specifically with respect to the treatment of nmDMD.

The forward-looking statements contained herein represent PTC's views only as of the date of this press release and PTC does not undertake or plan to update or revise any such forward-looking statements to reflect actual results or changes in plans, prospects, assumptions, estimates or projections, or other circumstances occurring after the date of this press release except as required by law.

To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/ptc-therapeutics-announces-workforce-reduction-as-part-of-operating-expense-management-plan-300240629.html>

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