PTC Announces Further Strategic Prioritization and Associated Reduction in Workforce

September 28, 2023

- Translarna CHMP opinion re-examination request to be submitted -

SOUTH PLAINFIELD, N.J., Sept. 28, 2023 /PRNewswire/ -- PTC Therapeutics, Inc. (NASDAQ: PTCT) announced today further strategic prioritization and associated workforce reduction. The portfolio prioritization continues the process initiated in May 2023 as the company continues to focus its resources on its differentiated, high potential R&D programs and on support of the robust global commercial infrastructure. The company also confirmed today its plans to submit the re-examination request for the CHMP opinion on Translarna.

"We remain confident that we have the data to address the concerns raised by CHMP in its negative opinion," said Matthew B. Klein, M.D., Chief Executive Officer, PTC Therapeutics. "The totality of evidence collected in three placebo-controlled trials and in the STRIDE registry provide clear evidence of Translarna's benefit. In addition, the patient and physician communities strongly believe in the benefits of Translarna and have shared their motivation to support the efforts to maintain authorization for the only approved Duchenne muscular dystrophy therapy in Europe."

The workforce reduction impacted approximately 25% of the organization, and primarily included employees working on early-stage research programs, employees at the gene therapy manufacturing facility located in Hopewell, NJ and associated SG&A functions. Implementation of these cost saving measures is expected to result in an approximate 20% reduction in annualized operating expenses compared to 2023 OPEX guidance.

"I would like to acknowledge the tremendous contribution of the PTC team members affected by the reduction in workforce," Klein continued. "The workforce and OPEX reductions continue the efforts we began in May to focus resources on key R&D programs and our commercial enterprise. PTC has a number of valuable assets that form the foundation of a promising future including the sepiapterin PKU program, the PTC518 Huntington disease program and the Evrysdi collaboration and royalty revenue."

About PTC Therapeutics, Inc.
PTC is a global biopharmaceutical company focused on the discovery, development and commercialization of clinically differentiated medicines that provide benefits to patients with rare disorders. PTC's ability to innovate to identify new therapies and to globally commercialize products is the foundation that drives investment in a robust and diversified pipeline of transformative medicines. PTC's mission is to provide access to best-in-class treatments for patients who have little to no treatment options. PTC's strategy is to leverage its strong scientific and clinical expertise and global commercial infrastructure to bring therapies to patients. PTC believes this allows it to maximize value for all its stakeholders. To learn more about PTC, please visit us at www.ptcbio.com and follow us on Facebook, Instagram, LinkedIn and Twitter at @PTCBio.

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Acronyms:
CHMP: Committee for Medicinal Products for Human Use
EMA: European Medicines Agency
OPEX: Operating Expenses
PKU: Phenylketonuria
SG&A: Selling, General and Administrative

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. All statements contained in this press release, other than statements of historic fact, are forward-looking statements, including statements regarding the extent, timing and financial aspects of the strategic prioritization and reduction in workforce; PTC's plans for interactions with the European Medicines Agency (EMA); the outcome of any re-examination process; the clinical utility and potential advantages of Translarna (ataluren); the future expectations, plans and prospects for PTC, including with respect to the expected timing of clinical trials and studies, availability of data, regulatory submissions and responses and other matters, future strategy, future operations, future financial position, future revenues, projected costs; and the objectives of management. Other forward-looking statements may be identified by the words, "guidance", "plan," "anticipate," "believe," "estimate," "expect," "intend," "may," "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 outcome of pricing, coverage and reimbursement negotiations with third party payors for PTC's products or product candidates that PTC commercializes or may commercialize in the future; the timing of and actual expenses incurred in connection with the strategic prioritization and reduction in workforce, which may be in different periods and may be materially higher than we estimate; the savings that may result from the strategic prioritization and reduction in workforce, which may be materially less than we expect;

PTC's ability to maintain its marketing authorization of Translarna for the treatment of nmDMD in Brazil, Russia, the European Economic Area (EEA) and other regions, including whether the European Medicines Agency (EMA) determines in the re-examination process that the benefit-risk balance of Translarna authorization supports renewal of such authorization or its conversion to a full approval; PTC's ability to complete Study 041, a randomized, 18-month, placebo-controlled clinical trial of Translarna for the treatment of nmDMD followed by an 18-month open-label extension, which is a specific obligation to continued marketing authorization in the EEA; PTC's ability to utilize results from Study 041 to support a marketing approval for Translarna for the treatment of nmDMD in the United States and a conversion to a standard marketing authorization in the EEA; whether investigators agree with PTC's interpretation of the results of clinical trials and the totality of clinical data from our trials in Translarna; significant business effects, including the effects of industry, market, economic, political or regulatory conditions; changes in tax and other laws, regulations, rates and policies; the eligible patient base and commercial potential of PTC's products and product candidates; PTC's scientific approach and general development progress; the sufficiency of PTC's cash resources and its ability to obtain adequate financing in the future for its 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 any product will receive or maintain regulatory approval in any territory, or prove to be commercially successful, including Translarna.

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.

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