



Protalix BioTherapeutics to Present Phase I PRX-115 Data in Late-Breaking Poster at ACR Convergence 2024

October 25, 2024

CARMIEL, Israel, Oct. 25, 2024 /PRNewswire/ -- Protalix BioTherapeutics, Inc. (NYSE American:PLX), a biopharmaceutical company focused on the development, production and commercialization of recombinant therapeutic proteins produced by its proprietary ProCellEx[®] plant cell-based protein expression system, today announced that data from the phase I clinical trial of PRX-115, the Company's recombinant PEGylated uricase product candidate in development for the treatment of uncontrolled gout, will be presented in a late-breaking poster at the American College of Rheumatology (ACR) Convergence 2024, being held November 14-19, 2024 at the Walter E. Washington Convention Center in Washington, D.C.

Details of the presentation are as follows:

ACR Convergence 2024

Title: Prolonged Plasma Urate-Lowering After a Single Intravenous Administration of PRX-115, a Novel PEGylated Uricase, in Participants with Elevated Urate Levels

Session: Late-Breaking Posters (L01-L14)

Session Date/Time: Monday, November 18, 2024, 10:30 AM – 12:30 PM Eastern Standard Time

Presenting Author: Orit Cohen Barak, Ph.D. (Protalix Ltd.)

Abstract Number: L05

The accepted abstract can be accessed on the ACR Convergence 2024 website at <https://acrabstracts.org/abstract/prolonged-plasma-urate-lowering-after-a-single-intravenous-administration-of-prx-115-a-novel-pegylated-uricase-in-participants-with-elevated-urate-levels/>. A copy of the poster will be made available on the Protalix website.

About Protalix BioTherapeutics, Inc.

Protalix is a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell-based expression system, ProCellEx. It is the first company to gain U.S. Food and Drug Administration (FDA) approval of a protein produced through plant cell-based in suspension expression system. This unique expression system represents a new method for developing recombinant proteins in an industrial-scale manner. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights to taliglucerase alfa for the treatment of Gaucher disease, Protalix's first product manufactured through ProCellEx, excluding in Brazil, where Protalix retains full rights. Protalix's second product, Elfabrio[®], was approved by both the FDA and the European Medicines Agency in May 2023.

Protalix has partnered with Chiesi Farmaceutici S.p.A. for the global development and commercialization of Elfabrio. Protalix's development pipeline consists of proprietary versions of recombinant therapeutic proteins that target established pharmaceutical markets, including the following product candidates: PRX-115, a plant cell-expressed recombinant PEGylated uricase for the treatment of uncontrolled gout; PRX-119, a plant cell-expressed long action DNase I for the treatment of NETs-related diseases; and others.

Forward-Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. The terms "expect," "anticipate," "believe," "estimate," "project," "may," "plan," "will," "would," "should" and "intend," and other words or phrases of similar import are intended to identify forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk and the final results of a clinical trial may be different than the preliminary findings for the clinical trial. Factors that might cause material differences include, among others: failure or delay in the commencement or completion of clinical trials which may be caused by several factors, including: slower than expected rates of patient recruitment; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; inability to satisfactorily demonstrate non-inferiority to approved therapies; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; inability to monitor patients adequately during or after treatment; and/or lack of sufficient funding to finance our clinical trials; the risk that our product candidates will not have the desired effects or will be associated with undesirable side effects or other unexpected characteristics; our dependence on performance by third-party providers of services and supplies, including without limitation, clinical trial services; the inherent risks and uncertainties in developing drug platforms and products of the type we are developing; the impact of development of competing therapies and/or technologies by other companies; potential product liability risks, and risks of securing adequate levels of related insurance coverage; the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of the operations of certain regulatory authorities and of certain of our suppliers, collaborative partners, licensees, clinical trial sites, distributors and customers; and other factors described in our filings with the U.S. Securities and Exchange Commission. The statements in this press release are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law.

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