Protalix BioTherapeutics Announces $20 Million Milestone Payment from Chiesi Global Rare Diseases

May 18, 2023

Milestone payment triggered by FDA approval of ELFABRIO® (pegunigalsidase alfa-iwxj) and payable within 30 days of approval

CARMIEL, Israel, May 18, 2023 /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 it is eligible to receive a $20 million milestone payment from its commercial partner, Chiesi Global Rare Diseases, a business unit of the Chiesi Group. The milestone payment was triggered by the approval by the U.S. Food and Drug Administration (FDA) of ELFABRIO (pegunigalsidase alfa-iwxj) for the treatment of adult patients with Fabry disease, which was announced on May 10, 2023, and is payable within 30 days of the FDA approval date.

"Receiving this milestone payment resulting from the FDA's approval of ELFABRIO is an important step for Protalix as it further to strengthens our financial position," said Dror Bashan, Protalix's President and Chief Executive Officer. "We continue to be grateful to our commercial partner, Chiesi, who has the global expertise to maximize the market potential of pegunigalsidase alfa."

On July 23, 2018, the Company's wholly-owned subsidiary entered into an Exclusive License and Supply Agreement with Chiesi Farmaceutici S.p.A., or Chiesi (the Chiesi US Agreement), pursuant to which the Company granted Chiesi an exclusive license to commercialize pegunigalsidase alfa in the United States. This followed the Exclusive License and Supply Agreement entered into with Chiesi on October 19, 2017 (the Chiesi Ex-US Agreement), pursuant to which Chiesi was granted an exclusive license to commercialize pegunigalsidase alfa in all markets outside of the United States. Under the two agreements, the Company has already received a total of $95.0 million in upfront payments and to cover development costs. In addition, under the two agreements, the Company is entitled to up to $1.0 billion in potential regulatory and commercial milestone payments, tiered royalties ranging from 15% to 40% of Chiesi's net sales in the United States and tiered royalties ranging from 15% to 35% of Chiesi's net sales outside the United States, as consideration for product supply.

On a proforma basis, including the receipt of the $20.0 million milestone payment, cash and cash equivalents as of May 18, 2023 is $51.6 million.

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 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. In addition, Protalix has partnered with Chiesi Farmaceutici S.p.A. for the global development and commercialization of PRX–102 (pegunigalsidase alfa).

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 severe 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 Protalix's current beliefs and expectations as to such future outcomes. Factors that might cause material differences include, among others: risks related to the commercialization of ELFABRIO; the likelihood that the FDA, European Medicines Agency (EMA) or other applicable health regulatory authorities will approve an alternative dosing regimen for ELFABRIO; risks related to the commercial success of Protalix's other product and product candidates, if approved; failure or delay in the commencement or completion of preclinical studies and clinical trials of our other product candidates 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; and inability to monitor patients adequately during or after treatment; delays in the approval or potential rejection of any applications

we file with the FDA, EMA or other health regulatory authorities for our other product candidates, and other risks relating to the review process; risks associated with the novel coronavirus disease, or COVID-19, outbreak, which may adversely impact our business, preclinical studies and clinical trials; the risk that the results of the clinical trials of our product candidates will not support the applicable claims of safety or efficacy, or that our product candidates will not have the desired effects or will be associated with undesirable side effects or other unexpected characteristics; risks related to our ability to maintain and manage our relationship with our collaborators, distributors or partners; 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 and institutions; potential product liability risks, and risks of securing adequate levels of product liability and other necessary insurance coverage; 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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