



## **Protalix BioTherapeutics Enters into an Exclusive Partnership with SarcoMed USA to Develop alidornase alfa for the Treatment of Pulmonary Sarcoidosis and Related Respiratory Diseases Via Inhaled Delivery**

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CARMIEL, Israel, Feb. 11, 2021 /PRNewswire/ -- Protalix BioTherapeutics, Inc. (NYSE American: PLX) (TASE: PLX), a biopharmaceutical company focused on the development production and commercialization of recombinant therapeutic proteins produced by its proprietary ProCellEx<sup>®</sup> plant cell-based protein expression system, today announced an exclusive worldwide license agreement with SarcoMed USA Inc. for alidornase alfa, or PRX-110, for use in the treatment of any human respiratory disease or condition including, but not limited to, sarcoidosis, pulmonary fibrosis, and other related diseases via inhaled delivery. Alidornase alfa is the Company's proprietary chemically-modified plant cell-expressed recombinant form of human deoxyribonuclease I (DNase I), administered through inhalation. SarcoMed USA was formed in 2017 to investigate if a novel DNase 1 compound could influence the chronic pulmonary inflammation seen in pulmonary sarcoidosis patients.

Under the terms of the agreement, SarcoMed will be responsible for the identification and selection of pharmaceutical candidates under the license, and the clinical research and development of such candidates. Protalix is entitled to an initial cash payment of \$3.5 million, subject to certain conditions, and to additional regulatory and commercial milestone payments and tiered royalties on net sales of products that are commercialized under the license agreement. In addition to the foregoing, the parties have agreed to commence negotiation of clinical and commercial supply agreements for alidornase alfa. As part of the arrangement, the parties have agreed to negotiate and sign a supply agreement within 60 days of the execution of the license agreement, and SarcoMed USA has the right to terminate the license agreement if the parties do not successfully do so.

"We are pleased to partner with SarcoMed USA, a privately-held company led by professionals with a wealth of experience in the research and development of pharmaceuticals," commented Dror Bashan, Protalix's President and Chief Executive Officer. "Most patients with pulmonary sarcoidosis do not show symptoms and do not realize they have the disease until it has progressed to later stages. Currently available treatment options vary significantly from patient to patient, and the treatments generally either control symptoms or improve the patient's lung function. A treatment that both controls symptoms and improves the patient's lung function is needed in the market today. We believe PRX-110 has the potential to be an exciting treatment option. Also, we believe this transaction further validates and enhances our development pipeline of drug candidates that can be produced through ProCellEx."

On July 21, 2020, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation for alidornase alfa for the treatment of sarcoidosis. The FDA grants Orphan Drug Designation to drugs or biologics intended to treat or prevent rare diseases or conditions that affect fewer than 200,000 individuals in the United States.

### **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<sup>®</sup>. Protalix was 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. Protalix's unique expression system represents a new method for developing recombinant proteins in an industrial-scale manner.

Protalix's first product manufactured by ProCellEx, taliglucerase alfa, was approved for marketing by the FDA in May 2012 and, subsequently, by the regulatory authorities of other countries. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights for taliglucerase alfa, excluding Brazil, where Protalix retains full rights.

Protalix's development pipeline consists of proprietary versions of recombinant therapeutic proteins that target established pharmaceutical markets, including the following product candidates: pegunigalsidase alfa, a modified version of the recombinant human  $\alpha$ -Galactosidase-A protein for the proposed treatment of Fabry disease; OPRX-106, an orally-delivered anti-inflammatory treatment; alidornase alfa or PRX-110, for the treatment of various human respiratory diseases or conditions; PRX-115, a plant cell-expressed recombinant PEGylated Uricase for the treatment of gout; and others. Protalix has partnered with Chiesi Farmaceutici S.p.A., both in the United States and outside the United States, for the development and commercialization of pegunigalsidase alfa.

### **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," "plan," "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: risks related to SarcoMed's and Protalix's compliance with the terms and conditions of the license agreement between the parties, and to their performance under the arrangement; risks related to SarcoMed's successful identification and development of product candidates under the license agreement; failure or delay in the commencement or completion of preclinical and clinical trials; risks associated with the novel coronavirus disease (COVID-19) outbreak, which may adversely impact our business, preclinical studies and clinical trials; risks related to any transactions we may effect in the public or private equity markets to raise capital to finance future research and development activities, general and administrative expenses and working capital; the risk that the results of the clinical trials of our product candidates will not support our claims of safety or efficacy, 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; risks related to the amount and sufficiency of our cash and cash equivalents; risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our outstanding notes or any other indebtedness; our dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services; delays in our preparation and filing of applications for regulatory approval; delays in the approval or potential rejection of any applications we file with the FDA or other health regulatory authorities, and other risks relating to the

review process; 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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