Chiesi Global Rare Diseases and Protalix BioTherapeutics Announce European Commission Approval of Additional Dosing Regimen of Every Four Weeks for Elfabrio® (pegunigalsidase alfa) ▼

Approved dosing regimen reduces the burden for eligible patients, their families, and the broader healthcare system by extending infusion interval from every-two-weeks to every-four-weeks for those stable with an enzyme replacement therapy (ERT)

With this decision, announced ahead of Fabry Disease Awareness Month in April, Chiesi Global Rare Diseases will work with countries across the EU to support broader access to this additional dosing schedule for the adult Fabry community

PARMA, Italy and CARMIEL, Israel – March 9, 2026 – Chiesi Global Rare Diseases, a business unit of the Chiesi Group established to deliver innovative therapies and solutions for people living with rare diseases, and Protalix BioTherapeutics, Inc. (NYSE American: PLX), a biopharmaceutical company focused on the discovery, development, production and commercialization of innovative therapeutics for rare diseases with significant unmet needs, today announced that the European Commission (EC) has approved the 2mg/kg every-4-weeks (E4W) dosing regimen for pegunigalsidase alfa in adults living with Fabry disease who are stable with an ERT. The EC decision follows the positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending the additional dosing regimen.

"The European Commission approval for 2mg/kg body weight E4W dosing regimen for pegunigalsidase alfa represents a meaningful advancement for adults living with Fabry disease and their families," said Giacomo Chiesi, Executive Vice President, Chiesi Global Rare Diseases. "Because Fabry disease requires lifelong treatment, the cadence of therapy inevitably becomes part of everyday life for patients and caregivers. By introducing an option that extends the infusion interval from every two weeks to every four weeks for eligible patients on stable ERT, we are offering families greater flexibility and the possibility to ease the overall burden of treatment. Ultimately, our goal is simple but profound: to help people spend less time managing their disease and more time living their lives. This milestone reflects our commitment to innovation that goes beyond delivering therapies—by listening to and understanding the real experiences of the Fabry community."

"In Fabry disease, long-term treatment decisions must balance disease management with the realities of lifelong therapy," said Prof. Aleš Linhart, DrSc, FESC. "The approval of pegunigalsidase alfa 2mg/kg every-4-weeks provides an additional option that may help reduce cumulative treatment burden for appropriate patients while maintaining continuity of care."

"This approval strengthens the treatment landscape for Fabry disease across the European Union by introducing an additional dosing approach that has the potential to enhance long-term care," said Dror Bashan, President and Chief Executive Officer, Protalix BioTherapeutics. "The authorization reflects not only scientific progress, but also a commitment to optimizing care delivery in a way that supports both patients and healthcare systems."

"For many people living with Fabry disease, treatment is a lifelong commitment that impacts nearly every aspect of daily life," said Mary Pavlou, President, Fabry International Network (FIN). "This approval allows for fewer infusion visits, helping reduce the ongoing burden on patients and families, allowing them to spend more time living their lives beyond treatment."

The EC approval is informed by results from an open-label, switch-over study, BRIGHT (formally PB-102-F50), designed to assess the adverse-event profile, efficacy, and pharmacokinetics (PK) of the alternative dosing regimen of pegunigalsidase alfa 2 mg/kg E4W for 52 weeks,[1] and its ongoing open-label extension study CLI-06657AA1-03 (formerly PB-102-F51).[2]

Protalix is entitled to a regulatory milestone payment of $25 million from Chiesi in connection with the EC's approval of the E4W dosing regimen.

About Fabry Disease

Fabry disease is a rare, inherited lysosomal storage disorder caused by mutations in the GLA gene, which leads to a deficiency of the enzyme alpha-galactosidase A. This deficiency results in an accumulation of a fatty substance called globotriaosylceramide (GL-3) in the body's cells, affecting the heart, kidneys, skin, nervous system, and other organs.[3] Fabry disease can cause a range of serious signs and symptoms, including fatigue, chronic pain, gastrointestinal issues, decreased ability to sweat, progressive kidney failure, heart complications, and increased risk of stroke.[4]

The condition affects both males and females and can present from childhood through adulthood, often with delayed diagnosis or misdiagnosis. While Fabry disease is rare, early detection and access to appropriate treatment — such as enzyme replacement therapy or pharmacological chaperone therapy — are critical in managing symptoms and slowing disease progression.[3]

About Chiesi Group

Chiesi is a research-oriented international biopharmaceutical group that develops and markets innovative therapeutic solutions in respiratory health, rare diseases, and specialty care. The company's mission is to improve people's quality of life and act responsibly towards both the community and the environment.

By changing its legal status to a Benefit Corporation in Italy, the US, France and Colombia, Chiesi's commitment to creating shared value for society as a whole is legally binding and central to company-wide decision-making. As a certified B Corp since 2019, Chiesi is part of a global community of businesses that meet high standards of social and environmental impact. The company aims to reach Net-Zero greenhouse gases (GHG) emissions by 2035.

With 90 years of experience, Chiesi is headquartered in Parma (Italy), with 31 affiliates worldwide, and counts more than 7,500 employees. The Group's research and development center in Parma works alongside 6 other important R&D hubs in France, the US, Canada, China, the UK, and Sweden.

About Chiesi Global Rare Diseases

Chiesi Global Rare Diseases is a business unit of the Chiesi Group established to deliver innovative therapies and solutions for people living with rare diseases. As a family business, Chiesi Group strives to create a world where it is common to have therapy for all diseases and acts as a force for good, for society and the planet. The goal of the Global Rare Diseases unit is to ensure equal access so as many people as possible can experience their most fulfilling life. The unit collaborates with the rare disease community around the globe to bring voice to underserved people in the health care system.

About Protalix BioTherapeutics, Inc.

Protalix is a biopharmaceutical company focused on the discovery, development, production and commercialization of innovative therapeutics for rare diseases. Protalix has researched, developed and currently manufactures two enzyme replacement therapies that are currently available in multiple markets. These therapies are recombinant therapeutic proteins expressed through Protalix' s proprietary plant cell-based expression system, ProCellEx®. ProCellEx is a unique plant cell-based system that enables Protalix to produce recombinant proteins in an industrial-scale manner with no exposure to mammalian cells. Protalix is the first company to gain US Food and Drug Administration (FDA) approval of a protein produced through plant cell-based in suspension expression system. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights to taliglucerase alfa, Elelyso®, for the treatment of Gaucher disease, excluding in Brazil, where Protalix retains full rights. Protalix has partnered with Chiesi Farmaceutici S.p.A. for the global development and commercialization of pegunigalsidase alfa, which was approved by both the FDA and the EMA in May 2023. Protalix' s development pipeline includes, among others, two proprietary versions of recombinant therapeutic proteins that target established pharmaceutical markets: PRX–115, a plant cell-expressed recombinant PEGylated uricase for the treatment of uncontrolled gout; and PRX–119, a plant cell-expressed long acting DNase I for the treatment of NETs-related diseases;

Protalix BioTherapeutics, Inc. 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 “anticipate,” “believe,” “estimate,” “expect,” “can,” “continue,” “could,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” 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: the risk that the EC will not approve the CHMP’s positive opinion recommending approval of the 2mg/kg every-4-weeks (E4W) dosing regimen for pegunigalsidase alfa in adults with Fabry disease; risks related to the commercialization of pegunigalsidase alfa; risks relating to pegunigalsidase alfa market acceptance, competition, reimbursement and regulatory actions, including as a result of the boxed warning contained in the FDA approval received for the product; delays in the approval or potential rejection of any applications filed with the FDA, EMA or other health regulatory authorities for Protalix' s product candidates, and other risks relating to the review process; the risk that the results of clinical trials will not support the applicable claims of safety or efficacy; ; risks relating to changes to published interim, topline or preliminary data from clinical trials; 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 risks relating to changes in healthcare laws, rules and regulations in the United States or elsewhere; and other factors described in our filings with the US Securities and Exchange Commission. The statements in this press release are valid only as of the date hereof and Protalix disclaims any obligation to update this information, except as may be required by law.

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