



€7.5 Million Granted to Collaborative PROTO Project led by Charité to Study Pluri's PLX-PAD Cells for Osteoarthritis Treatment

HAIFA, Israel, September 6, 2022 – Pluri Inc. (Nasdaq: PLUR) (TASE: PLUR) (“Pluri” or the “Company”) (formerly known as Pluristem Therapeutics, Inc.), a leading biotechnology company, today announced that a €7.5 million non-dilutive grant from the European Union’s Horizon Europe program has been awarded to PROTO (Advanced PeRsOnalized Therapies for Osteoarthritis), an international collaboration led by Charité, Berlin Institute of Health Center for Regenerative Therapies. The goal of the PROTO project is to utilize Pluri’s PLX-PAD cells in a Phase I/IIa study for the treatment of mild to moderate knee osteoarthritis (OA). The project is currently under grant agreement preparation number 101095635. Final approval of the grant is subject to completion of the consortium and Horizon Europe grant agreements. The funds from the grant are expected to be allocated between Pluri and other members of the consortium in accordance with budget and work packages which will be determined by the consortium.

The Phase I/IIa study will be carried out by Charité, Pluri and other members of the international consortium under the leadership of Professor Tobias Winkler, Principal Investigator (PI) at the Berlin Institute of Health Center for Regenerative Therapies, Julius Wolff Institute and Center for Musculoskeletal Surgery. Professor Winkler was also the lead PI in the Phase II and Phase III muscle regeneration studies using Pluri’s PLX-PAD cells.

“Having evaluated PLX-PAD in other advanced-stage clinical studies, we see clear potential for this cell-based product to treat OA,” Professor Winkler said. “The immunomodulatory properties of PLX-PAD appear well suited to address the significant chronic inflammatory components that underly OA pathophysiology, and we are eager to advance the product candidate into a clinical study for this indication. Financial support from Horizon Europe may accelerate this critical process.”

“This award underscores the vast potential of our PLX-PAD cells to treat chronic disease with regenerative medicine,” said Yaky Yanay, Pluri’s CEO and President. “We are proud to expand our collaboration with Professor Winkler and Charité and receive support from Horizon Europe for our platform technology and cell product candidates, as we advance Pluri’s clinical pipeline and seek new cell-based solutions to longstanding health challenges.”

OA is one of the most common chronic articular diseases, with a global prevalence of 16% in the adult population¹. OA is the third most rapidly growing disease associated with disability², showing an increase of 30% over the past decade, currently affecting more than 500 million people worldwide and about 50 million in Europe³. Globally, symptomatic OA affects ~10% of men and 18% of women over 60 years of age, with knee being the most commonly affected joint⁴. OA also represents a huge healthcare burden with U.S. indirect costs amounting to 1% of the gross national product⁵.

There is currently no effective disease-modifying treatment for OA, only symptomatic treatment at a late stage. OA increases the risks of joint inflammation, pain, stiffness, swelling, disability, morbidity and

¹ [Cui et al., 2020, PMID: 34505846](#)

² [Hawker et al., 2019, PMID: 31621562](#)

³ [Hunter et al., 2020, PMID:33159851](#)

⁴ [A. Jaiswal et al., 2021](#)

⁵ [Kingsbury et al., 2014, PMID: 24489012](#)



mortality, and it reduces quality of life and work performance. OA might lead to reduced mobility and chronic disability and is associated with cardiovascular and metabolic co-morbidities.

PLX-PAD is an innovative anti-inflammatory allogeneic placental cell therapy product candidate to treat patients with mild to moderate knee OA as a direct approach to reduce inflammation and cartilage degeneration.

About Pluri Inc.

Pluri is pushing the boundaries of science and engineering to create cell-based products for commercial use and is pioneering a biotech revolution that promotes global wellbeing and sustainability. The Company's technology platform, a patented and validated state-of-the-art 3D cell expansion system, advances novel cell-based solutions for a range of initiatives— from medicine and climate change to food scarcity, animal cruelty and beyond. Pluri's method is uniquely accurate, scalable, cost-effective, and consistent from batch to batch. Pluri currently operates in the field of regenerative medicine and food-tech and aims to establish partnerships that leverage the Company's 3D cell-based technology to additional industries that require effective, mass cell production. To learn more, visit us at www.pluri-biotech.com or follow us on [LinkedIn](#) and [Twitter](#).

About Osteoarthritis and the Consortium

OA is the most common form of arthritis worldwide. Chronic low-grade inflammation in the articular environment causes cartilage degeneration at an early disease stage, resulting in chronic pain, disability and loss of independence due to progressive joint destruction. To date, no disease modifying treatment is available to sustainably combat low-grade inflammation in early-stage OA patients. Biomechanical causes for intra-articular inflammation and OA development have been detected in specific patient groups. The PROTO consortium strives to implement new evidence- and patient-centered treatment strategies for early- and pre-disease stages. For the first time, early-stage knee OA patients will be treated with local PLX-PAD injections, a novel allogeneic cell therapy product with distinct anti-inflammatory capacities that may halt or revert disease progression. Secondly, patients recovering from anterior cruciate ligament reconstructions with pathological gait patterns leading to knee OA, will be treated with a personalized sensor-based digital training intervention. We intend to prevent health to disease transition by restoring physiological movement and reducing joint inflammation. To assess treatment success in early- and pre-stage OA, PROTO gathers scientific and clinical specialists who have genuinely shaped clinical, radiological and biomarker outcome parameters for OA in recent years. This will be the first time that these renowned experts join forces to analyze, stratify and compare fundamentally novel disease modifying treatment strategies for OA in one consortium. PROTO was developed with the help of patient organizations, industry partners and research societies. Restoring physiological joint homeostasis at an early disease stage may be the key to understanding health to disease progression in OA. Targeting this 'window of opportunity' may fundamentally change the way OA is treated today and in the future.

Safe Harbor Statement

This press release contains express or implied forward-looking statements within the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. For example, Pluri is using forward-looking statements when it discusses the expected receipt of the grant from the Israel Innovation Authority, the potential for PLX-PAD to be used to treat OA, that the receipt of the grant may accelerate the clinical study of PLX-PAD, that the grant underscores the potential for PLX-PAD cells to treat chronic disease and that it is advancing its clinical pipeline and seeking new cell-based solutions to longstanding health challenges, that targeting the current 'window of opportunity' may fundamentally change the way



OA is treated today and in the future and the potential of the Company's products and solutions to promote global wellbeing and sustainability. These forward-looking statements and their implications are based on the current expectations of the management of Pluri only and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements about Pluri: changes in technology and market requirements; Pluri may encounter delays or obstacles in launching and/or successfully completing its clinical trials, if necessary; its products may not be approved by regulatory agencies, its technology may not be validated as it progresses further and its methods may not be accepted by the scientific community; it may be unable to retain or attract key employees whose knowledge is essential to the development of its products; unforeseen scientific difficulties may develop with its processes; its products may wind up being more expensive than it anticipates; results in the laboratory may not translate to equally good results in real clinical settings; its patents may not be sufficient; its products may harm recipients or consumers; changes in legislation with an adverse impact; inability to timely develop and introduce new technologies, products and applications; loss of market share and pressure on pricing resulting from competition, which could cause the actual results or performance of Pluri to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Pluri undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting Pluri reference is made to Pluri's reports filed from time to time with the Securities and Exchange Commission.

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