U.S. National Institutes of Health to Fund $4.2 Million Contract to Advance Development of Pluri's PLX-R18 in Conjunction with U.S. DoD as a Medical Countermeasure for Hematopoietic Acute Radiation Syndrome

- *Pluri's cell therapy is designed to be the first in class, effective treatment for ionizing radiation poisoning in the event of a large-scale nuclear incident.*
- *The work specified by the contract is based on communications with the FDA and will enable Pluri to make significant progress toward marketing approval for PLX-R18.*
- *PLX-R18 is developed with the intention of being eligible for purchase by the U.S. Strategic National Stockpile as a medical countermeasure for exposure to nuclear radiation, following FDA approval.*

HAIFA, Israel, July 11, 2023 – Pluri Inc. (Nasdaq: PLUR) (TASE: PLUR) ("Pluri" or the "Company"), a leading biotech company that transforms cells into solutions that promote wellbeing and sustainability, today announced that it has signed a three year $4.2M contract with the U.S. National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). Pluri will collaborate with the U.S. Department of Defense's Armed Forces Radiobiology Research Institute (AFRRI)/Uniformed Services University of Health Sciences (USUHS) in Maryland, USA to further advance the development of its PLX-R18 cell therapy as a potential novel treatment for Hematopoietic Acute Radiation Syndrome (H-ARS). H-ARS is a deadly disease that can result from nuclear disasters and radiation exposure.

Recent geo-political events have reinforced the need for the global community to better prepare for nuclear disasters, such as seeking new medical treatments that are more cost-efficient and scalable than current options that can be proactively administered in advance of a potential nuclear event. H-ARS, also known as radiation poisoning, is caused by exposure to life-threatening amounts of ionizing radiation, such as what may occur during nuclear/radiological

accidents, terrorist activities and warfare. H-ARS is characterized by dose dependent bone marrow depression, leading to life-threatening neutropenia, thrombocytopenia and anemia, and possible death.

This contract supports Pluri's goal to achieve marketing approval for PLX-R18 with the U.S. Food and Drug Administration (FDA), which could qualify the product to be purchased for the U.S. Strategic National Stockpile as a medical countermeasure for exposure to radiation. The FDA previously cleared an Investigational New Drug (IND) application for PLX-R18 for the treatment of ARS in the case of nuclear events and granted it Orphan Drug Designation.

Pluri will collaborate with Prof. Vijay K. Singh of AFRRI, a world-renowned expert in radiation treatments. His laboratory's primary research interest is to develop radiation countermeasures for ARS.

"The current time calls for us to accelerate the development and accessibility of radiation treatments, especially as geopolitical instability rises, and nuclear power plants face the threat of warfare," said Pluri CEO and President Yaky Yanay. "Through this strategic contract with NIAID, we believe that we can realize our mission of making PLX-R18 readily available for emergency preparedness. We look forward to collaborating with Prof. Singh and AFRRI to explore the potential of PLX-R18 as a uniquely, scalable treatment for H-ARS."

Prof. Singh added, "PLX-R18's potential as a medical countermeasure for H-ARS is supported by robust human and animal data, making it a unique asset for further investigation. I'm eager to commence our collaborative study with Pluri and have high expectations for results."

Prior studies funded by the NIH/NIAID and conducted in accordance with the FDA's Animal Rule pathway demonstrated that PLX-R18 administered to animals after radiation exposure for H-ARS significantly increased survival rates from 29% in the control group to 97% in the treated group ($p<0.001$). Studies conducted by the U.S. Department of Defense (DoD) have shown that PLX-R18, administered as a prophylactic measure 24 hours before radiation exposure, and again 72 hours after exposure, resulted in a significant increase in survival rates, from 4% survival rate in the placebo group to 74% in the treated group (log-rank test $p< 0.0001$). In addition, the data show a significant increase in recovery of white blood cells ($p = 0.0047$), platelets ($p = 0.0070$), neutrophils ($p = 0.0003$) and lymphocytes ($p = 0.0025$) counts compared to administration of vehicle, and a favorable safety profile[i].

Additionally, PLX-R18 was tested in humans with incomplete hematopoietic recovery following Hematopoietic Cell Transplantation (HCT) and was well tolerated with a favorable safety profile. Patients treated with PLX-R18 showed an increase in all three blood cell types compared to the baseline with platelets ($p<0.001$), hemoglobin ($p=0.02$) and neutrophils ($p=0.15$) levels increasing, as early as 1 month following PLX-R18 administration and enduring up to 12 months following treatment, while experiencing a significant reduction in mean number of transfused units from a monthly 5.09 to 0.55 for platelets ($p=0.045$) and 2.91 to 0 for red blood cells ($p=0.0005$) over 12 months of follow-up.

About the Contract

The purpose of the contract is to support the development of PLX-R18 as a novel cellular medical countermeasure for the prevention, mitigation and treatment of all aspects of H-ARS. Through *in vitro*, *ex vivo* and animal studies, the aim is to demonstrate the efficacy of PLX-R18, manufactured according to cGMP standards, as a treatment even when administered 48 hours or later following radiation exposure. Following *in vitro* and *ex vivo* studies, mice that have been exposed to total body irradiation will be dosed with clinical grade PLX-R18 as well as CRISPR/Cas9-edited PLX-R18 cells. Dose regimen, radiation levels, and corresponding increasing survival will be assessed, as well as analysis into the mechanisms of action.

About PLX-R18

PLX-R18 is a novel cell-based medicinal product, comprised of human placenta derived stromal cells delivered through intramuscular (*im*) injection. The living cells adaptively secrete a cocktail of active hematopoietic factors. These factors act together to produce optimal therapeutic efficacy by facilitating the recovery of hematopoietic progenitor cells in the bone marrow and the regeneration of multiple blood lineage cell counts in the peripheral blood. Preclinical studies have shown that PLX-R18 cells ameliorate or prevent the toxicity of H-ARS. Further preclinical data from trials conducted by the NIH, the Charité in Berlin, Indiana University (Prof. Christie M Orschell) AFRRI (Dr. Sanchita Ghosh) and other prominent research institutions, have shown that PLX-R18 cells secrete a range of specific factors that salvage and trigger the regeneration of bone marrow hematopoietic cells, thereby supporting the recovery of blood cell production. With its capabilities, PLX-R18 could potentially be used in several indications to treat a broad range of hematologic disorders, which together constitute a substantial global market.

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 cGMP-grade 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, food-tech and biologics 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.

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 potential value of the contract and program, that the contract supports its goal to achieve marketing approval for PLX-R18 with the FDA, the belief that the strategic contract with NIAID can help it realize its mission of making PLX-R18 readily available for emergency preparedness and the potential benefits to be derived from the use of PLX-R18. 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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[i] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9601513/