



U.S. National Institutes of Health Exercises Option to Fund \$1.4 Million 2nd Year Budget for Pluri's PLX-R18 Acute Radiation Syndrome Contract

- *As part of Pluri's previously announced \$4.2 million 3-year [contract](#) with the U.S. National Institute of Allergy and Infectious Diseases (NIAID), the option for the second year of the contract has been exercised to fund manufacturing, in-vitro, and in-vivo studies of Pluri's cell therapy*
- *PLX-R18 is designed to be a first in class, effective treatment for ionizing radiation injuries that could be anticipated in the wake of a large-scale nuclear incident*
- *Work during the contract period is expected to make further progress toward marketing approval for PLX-R18 as a medical countermeasure for exposure to radiation and lead to PLX-R18 becoming eligible for procurement by the [U.S. Strategic National Stockpile](#), following FDA approval*

HAIFA, Israel – June 6 , 2024 – [Pluri Inc.](#) (Nasdaq:PLUR) (TASE:PLUR) ("Pluri" or "the Company), a leading biotechnology company that transforms cells into solutions, today announced the U.S. National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), has exercised its option for year two of the three-year \$4.2 million contract it entered into with Pluri in July 2023. During the 12 months from July 1, 2024 through June 30, 2025, the NIAID will provide \$1.4 million for the Company to manufacture the PLX-R18 cell therapy and to conduct both in vitro and in vivo studies to develop PLX-R18 as a potential novel treatment for hematopoietic complications of the acute radiation syndrome (H-ARS).

H-ARS is caused by exposure to life-threatening amounts of ionizing radiation, such as that which may occur during a radiological or nuclear accident, terrorist activities, and/or warfare. The condition is characterized by dose-dependent bone marrow depression, leading to neutropenia, thrombocytopenia, and anemia, and possibly death. The U.S. Food and Drug Administration (FDA) previously [approved](#) an Investigational New Drug application for PLX-R18 for the treatment of H-ARS in the case of nuclear or radiological or incidents and [granted](#) it Orphan Drug Designation.

Over the past year, Pluri has collaborated with the U.S. Department of Defense's (DoD) Armed Forces Radiobiology Research Institute at the Uniformed Services University of Health Sciences in Bethesda, Maryland, resulting in significant advancements in the development of PLX-R18 as a potential treatment for H-ARS.

"PLX-R18 is being developed as a next-generation countermeasure against the damage caused by ionizing radiation, aiming to treat single-agent neutropenia, thrombocytopenia, and anemia. We would like to thank NIAID for its trust and for choosing to exercise its second-year option,



this action validates the potential of PLX-R18 to treat H-ARS,” said Yaky Yanay, Chief Executive Officer and President of Pluri. “We are pleased to continue working with the NIH and the DoD’s Armed Forces Radiobiology Research Institute, to advance this potential treatment for a truly devastating medical condition, especially in light of recent geopolitical events and the global threat of nuclear disasters.”

PLX-R18 has been safely tested in both humans and animals. [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 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 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 cell ($p = 0.0047$), platelet ($p = 0.0070$), neutrophil ($p = 0.0003$) and lymphocyte ($p = 0.0025$) counts compared to administration of vehicle, and also demonstrate a favorable safety profile.

PLX-R18 was tested in humans with incomplete hematopoietic recovery following hematopoietic cell transplantation 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 platelet ($p < 0.001$), hemoglobin ($p = 0.02$) and neutrophil ($p = 0.15$) 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 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 well-being 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 challenges— 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, foodtech and agtech. The Company also offers Contract Development and Manufacturing Organization (CDMO) services. Pluri establishes partnerships that leverage the Company’s proprietary 3D cell-based technology across various industries that require effective, mass cell production. To learn more, visit us at www.pluri-biotech.com or follow Pluri on [LinkedIn](#) and [X](#) (formerly known as 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 benefits to be derived from the use of PLX-R18; its collaborations with strategic partners; its regulatory strategy; and that work during the contract period is expected to make further progress toward marketing approval for PLX-R18 as a medical countermeasure for exposure to nuclear radiation and lead to PLX-R18 becoming eligible for purchase by the U.S. Strategic National Stockpile. 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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