



## **Pluristem and New York Blood Center to Collaborate in Evaluating PLX-R18 as an Adjuvant Therapy to Umbilical Cord Blood Transplantation, Winning \$900,000 Funding From BIRD**

- Prior research has suggested that PLX-R18 helps cord blood cells to engraft more rapidly and effectively
- Grant of \$900,000 from Israel-U.S. Binational Industrial Research and Development Foundation (BIRD) to fund the research
- Constitutes a 3rd potential hematologic indication for PLX-R18

**HAIFA, ISRAEL, December 27, 2016** -- [Pluristem Therapeutics Inc.](http://www.pluristem.com) (NasdaqCM: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, today announced that it will collaborate with the New York Blood Center (NYBC) on preclinical studies of its Placental eXpanded (PLX)-R18 cells to enhance the efficacy of umbilical cord blood (UCB) transplantation. The project has been selected to receive a conditional award of \$900,000 from Israel-U.S. Binational Industrial Research and Development Foundation (BIRD). Per the terms of the project, Pluristem will provide the PLX-R18 cells and the NYBC will be responsible for conducting and supporting the studies.

Umbilical cord blood cells, a rich supply of stem cells, are transplanted to restore a patient's bone marrow cells. Stem cell transplant can treat leukemia, lymphoma, immune deficiency, genetic diseases and other cancers. Prior preclinical research has suggested that PLX-R18 helps cord blood stem cells to engraft more rapidly and effectively than if they are administered alone. The ability to affect speed and extent of engraftment is clinically important, because a patient remains vulnerable to severe infection and other serious complications until transplanted stem cells begin to make mature blood cells.

Dr. Beth H. Shaz, Senior Vice President and Chief Medical and Scientific Officer of NYBC, commented, "This is an exciting opportunity to begin collaborating with Pluristem, using our considerable expertise and world-class facilities to explore the potential of Pluristem's cells in a key hematologic research area. Based on previous data, we believe that PLX-R18 cells might contribute to a significant improvement in the success rate of umbilical cord blood transplants."

"PLX-R18 is emerging as a promising multifactorial treatment for hematologic conditions. It can potentially speed engraftment of umbilical cord blood cells and stimulate the production of all

three types of blood cells: white and red blood cells, as well as platelets. We believe this offers a clear advantage over current therapies. We are thankful for the BIRD foundation for their support of this important project,” stated Pluristem Chairman and CEO Zami Aberman.

“Data from NYBC’s studies are expected to help round out the growing body of evidence for PLX-R18’s role in improving outcomes for patients living with hematologic diseases. We are very pleased that NYBC, a trusted source of cord blood and cellular therapies for practicing physicians and hospitals, is exploring the potential of PLX-R18’s use for future clinical applications,” Mr. Aberman added.

Support for the transplantation of CD34+ cells from umbilical cord blood constitutes the third potential hematologic indication for PLX-R18. The U.S. Food and Drug Administration has cleared a Phase I clinical trial of PLX-R18 in the treatment of insufficient hematopoietic recovery following hematopoietic stem cell transplantation; the transplanted cells in this study can originate from bone marrow, peripheral blood, or umbilical cord blood. In addition, the U.S. National Institutes of Health’s National Institute of Allergy and Infectious Disease (NIAID) is currently conducting a dose-evaluation study of PLX-R18 in large animals, in advance of a possible pivotal trial for PLX-R18 in the treatment of Acute Radiation Syndrome (ARS) via the Animal Rule regulatory pathway. Human efficacy studies will not be required for FDA approval.

#### **About PLX-R18**

PLX-R18 is Pluristem’s second cell therapy product in development. It is designed to treat bone marrow that is unable to produce enough blood cells due to a variety of causes including ARS, certain cancers or cancer treatments, or immune-mediated bone marrow failure. Pluristem received FDA clearance to initiate a U.S. Phase I trial of PLX-R18 in incomplete bone marrow recovery following hematopoietic stem cell transplantation. Preclinical data from trials conducted by Hadassah Medical Center, the National Institutes of Health and other prominent research institutions have shown that PLX-R18 cells secrete a range of specific proteins that trigger the regeneration of bone marrow hematopoietic stem cells, thereby supporting the recovery of blood cell production. The NIH’s NIAID is supporting and conducting trials of PLX-R18 as a treatment for ARS, a severe, life-threatening condition caused by exposure to high levels of radiation such as would occur with a nuclear catastrophe. With its capabilities, PLX-R18 could potentially treat a broad range of hematologic indications, which together constitute a substantial global market.

#### **About New York Blood Center**

New York Blood Center (NYBC) is a nonprofit organization that is one of the largest independent, community-based blood centers in the country. Founded in 1964, NYBC, along with its partner organizations Community Blood Center of Greater Kansas City (CBC) and Innovative Blood Resources (IBR), based St. Paul, Minnesota, collect approximately 3,300 units of blood products each day, serving local communities of more than 25 million people in New York, New Jersey,

parts of Connecticut and Pennsylvania, the Kansas City metropolitan area, Minnesota, and Nebraska.

NYBC and its partners, through its Comprehensive Cell Solutions, also provide a wide array of transfusion-related medical services, while NYBC's National Cord Blood Program (NCBP) at the Howard P. Milstein Cord Blood Center is home to the world's largest public cord blood bank. Comprehensive Cell Solutions is also home to a renowned research institute, which – among other milestones – led to the development of a Hepatitis B vaccine and innovative blood purification technology.

### **About Pluristem Therapeutics**

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The Company has reported robust clinical trial data in multiple indications for its patented PLX (PLacental eXpanded) cells. The cells release a range of therapeutic proteins in response to inflammation, ischemia, hematological disorders, and radiation damage. PLX cell products are grown using the Company's proprietary three-dimensional expansion technology. They are off-the-shelf, requiring no tissue matching prior to administration.

Pluristem has a strong intellectual property position; Company-owned and operated, GMP-certified manufacturing and research facilities; strategic relationships with major research institutions; and a seasoned management team.

### **Safe Harbor Statement**

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and federal securities laws. For example, forward-looking statements are used in this press release when we discuss obtaining a \$900,000 grant from the BIRD Foundation and the expected use of the grant, when we discuss the potential of PLX-R18 cells to accelerate the successful engraftment of transplanted cord blood cells and to be a multifactorial treatment for hematologic conditions, when we discuss our belief that PLX-R18 offers an advantage over current therapies; when we discuss the expectation that data from the research will help round out the growing body of evidence for PLX-R18's role in improving outcomes for patients living with hematologic diseases, when we discuss the expected commencement of the preclinical studies of our PLX-R18 cells as support for CD34+ umbilical cord blood transplantation and the expected results of these studies, when we discuss the advancement of a possible pivotal trial for PLX-R18 in the treatment of ARS via the Animal Rule regulatory pathway, and when we discuss PLX-R18's potential to treat a broad range of hematologic indications, which together constitute a substantial global market. Further, Pluristem may not be granted the award if a Cooperation and Project Funding Agreement is not signed by March 31, 2017. These forward-looking statements and their implications are based on the current expectations of the management of Pluristem 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: changes in technology and market requirements; we may encounter delays or obstacles in launching and/or successfully completing our clinical trials; our products may not be approved by regulatory agencies, our technology may not be validated as we progress further and our methods may not be accepted by the scientific community; we may be unable to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties may develop with our process; our products may wind up being more expensive than we anticipate; results in the laboratory may not translate to equally good results in real clinical settings; results of preclinical studies may not correlate with the results of human clinical trials; our patents may not be sufficient; our products may harm recipients; changes in legislation; 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 Pluristem to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Pluristem 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 Pluristem, reference is made to Pluristem's reports filed from time to time with the Securities and Exchange Commission.

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