



## **Pluristem Recaps Investor & Analyst Call Reviewing European Investment Bank's €50 Million Financing**

- **Elaborating on agreement terms and tranches schedule**
- **Provides update on cash position and clinical program**

**HAIFA, Israel, April 30, 2020** - **Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI)** (the "Company"), a leading regenerative medicine company developing a platform of novel biological therapeutic products, today provided a summary of an Investor & Analyst Call (the "Call") conducted on April 30, 2020, in conjunction with the European Investment Bank ("EIB") and kENUP Foundation. The purpose of the Call was to discuss the €50 million venture loan financing (the "Financing") to Pluristem by the EIB and followed a signing ceremony of the Financing contract on Innovation Cell Therapies (EGFF) between the parties.

Speakers on the Call included Pluristem's CEO and President, Yaky Yanay, and the Company's, CFO, Chen Franco-Yehuda; the kENUP Foundation's Chairman Holm Keller; and the EIB's Investment Officer, Anna Stodolkiewicz. During the Call, the speakers presented details regarding the EIB's Financing to Pluristem in support of the Company's research and development in the European Union to further advance its regenerative cell therapy platform, and to assist in moving its pipeline to market, with a special focus on clinical development of PLX cells as a treatment for complications associated with COVID-19. The presentation was followed by a question and answer session with financial and industry analysts.

Pluristem CFO, Chen Franco-Yehuda, summarized the EIB's Financing to Pluristem and provided an update on the Company's financial highlights.

- A total of up to €50 million is made available from the EIB to Pluristem through three tranches over a period of 36 months. The Financing will not exceed 50% of the total cost of the applicable project. Each tranche will be disbursed following the achievement of certain clinical, regulatory and scaleup milestones. The first tranche is €20 million, followed by a second tranche of €18 million, and a third tranche of €12 million.
- Each tranche will be treated independently from the others, with the following repayment dates: a) the first tranche of €20 million will be repaid 5 years following its disbursement with a 4% deferred annual interest, paid at maturity of the tranche; b) the second tranche of €18 million will be repaid 5 years following its disbursement with a 3% deferred annual interest, paid at maturity of the tranche, and 1% annual cash interest; and c) the third tranche €12 million will be repaid in 2 annual installments starting on the 4th anniversary from its disbursement with 2% deferred annual interest, paid at maturity of the tranche, and 1% annual cash interest.

- Royalties will be paid on Pluristem's consolidated revenues if generated between fiscal years 2024-2030, pro-rated to the amount disbursed from the EIB Financing, as follows:
  - a) 2.3% of consolidated annual revenues applying on the portion of less than \$350 million;
  - b) 1.2% of consolidated annual revenues applying on the portion between \$350 million and \$500 million;
  - c) 0.2% of consolidated annual revenues exceeding \$500 million. Pluristem can buy back the royalty commitment for a payment that will not exceed €50 million.
- Pluristem has cash and deposits of approximately \$44 million as of April 30, 2020 as compared to approximately \$17 million on December 31, 2019. Since January 1, 2020, funding has been obtained through an At-the-Market (ATM) facility, warrant exercises and grants from the European Horizon 2020 program. Pluristem's currently available resources, including the EIB Financing, assuming all milestones are reached and applicable payments are made, are expected to total approximately \$100 million and are expected to fund Pluristem's operations through the coming 3 years.

Pluristem CEO and President, Yaky Yanay, provided an update on the Company's clinical programs. An Investigational New Drug (IND) application has been filed with the U.S. Food and Drug Administration ("FDA") and a Clinical Trial Authorization (CTA) application has been submitted in Europe, starting with Germany and Italy. Pluristem intends to commence Phase II studies of PLX cell therapy in the treatment of complications arising from COVID-19 as soon as it receives clearance from regulators in the U.S. and Europe. Anticipating responses in the next few weeks, Pluristem aims to complete enrollment and treatment in few months, by utilizing its logistical and technological competitive advantages to support effective enrollment. In parallel, the Company will conduct an Expanded Access Program in U.S and Europe. The EIB Financing, once received, will allow the Company to expedite the process.

- **The critical limb ischemia (CLI) Phase III study** is advancing with more than 80% patients enrolled; enrollment has slowed in April, 2020. Pluristem is now finalizing discussions with the FDA and European Medicines Agency (EMA) regarding the interim data readout, confirming understandings on endpoint, timing, and procedures for cleaning data during COVID-19 limitations.
- Expected announcement of the interim readout top line results to be delayed to the beginning of the fourth quarter of calendar year 2020. The Company is and will continue to closely follow the guidelines that will enable access to the clinical sites to clean the data prior to data lock.
- The Company will provide guidelines for expected end of enrollment of the entire study once having better clarity of the impact of COVID-19 on the enrollment rate.
- **The Phase III study on muscle regeneration following hip fracture** is more than 60% enrolled; enrollment has slowed in April, 2020. Pluristem has been working hard to secure Short Physical Performance Battery (SPPB) data capture, working with the sites on home monitoring.

- The Company will provide guidelines for expected end of enrollment of the entire study once having better clarity of the impact of COVID-19 on the enrollment rate.

“By leveraging our logistical and technological competitive advantages, we believe we can rapidly and effectively enroll and treat COVID-19 patients in the U.S. and Europe. We believe that the EIB’s Financing allows us to expedite this process and we are immensely grateful for their support. While we plan to treat COVID-19 patients through a clinical trial framework, we plan to have parallel expanded access and compassionate use programs in the U.S., Europe, and Israel, through which we can continue to deliver our potentially life-saving PLX therapy to patients in need,” concluded Mr. Yanay.

Holm Keller, Chairman of kENUP Foundation commented regarding Pluristem’s activity, “Pluristem is an exceptionally innovative company advancing regenerative medicine solutions with cell manufacturing technologies that can truly make cell therapy available in mass quantities and efficiently. It is for this reason that kENUP was compelled to bring Pluristem and the EIB together in partnership to accelerate the commercialization of regenerative medicine.”

Anna Stodolkiewicz, Investment Officer of the EIB said: “Through our financing, we aim to support Pluristem in addressing life threatening medical problems. Be it COVID-19, critical limb ischemia or the recovery following hip fracture - all of them disproportionately affect an aging population. We especially appreciate that Pluristem seeks to accelerate regenerative, non-invasive treatments that ease the burden on patients and Europe’s healthcare systems alike. In addition, Pluristem will create highly skilled jobs and economic opportunities in the EU.”

#### **About the European Investment Bank**

The European Investment Bank (EIB) is the long-term lending institution of the European Union, owned by its Member States. It makes long-term finance available for sound investment in order to contribute towards EU policy goals.

#### **Investment Plan for Europe**

The Investment Plan for Europe (the Juncker Plan) is one of the EU's key actions to boost investment in Europe, thereby creating jobs and fostering growth. To this end, smarter use will be made of new and existing financial resources. The EIB Group, consisting of the European Investment Bank and the European Investment Fund, is playing a vital role in this investment plan. With guarantees from the European Fund for Strategic Investments (EFSI), the EIB and EIF are able to take on a higher share of project risk, encouraging private investors to participate in the projects. In addition to EFSI, the new European Investment Advisory Hub (EIAH) helps public and private sector project promoters to structure investment projects more professionally. The projects and agreements approved under EFSI (European Fund for Strategic Investments) so far are expected to mobilise almost €466 billion of investments and will benefit over 1 million start-ups and SMEs (Small Medium Enterprises) in the 27 Member States.

**About kENUP Foundation**

kENUP is a global partnership in innovation, promoting research-based innovation for Europe with public and societal benefit. kENUP develops projects to pursue market-leading positions for European innovation businesses. In this capacity, kENUP is supporting the execution of the European Fund for Strategic Investments (EFSI, the so-called “Juncker Plan”), alongside its successor EFSI 2.0 and of the current InvestEU Fund. kENUP is a not-for-profit organization established as a foundation in the Republic of Malta by Public Deed on November 6, 2014. kENUP’s activities are published in the European Transparency Register.

**About Pluristem Therapeutics**

Pluristem Therapeutics Inc. is a leading regenerative medicine company developing novel placenta-based cell therapy product candidates. The Company has reported robust clinical trial data in multiple indications for its patented PLX cell product candidates and is currently conducting late stage clinical trials in several indications. PLX cell product candidates are believed to release a range of therapeutic proteins in response to inflammation, ischemia, muscle trauma, hematological disorders and radiation damage. The cells are grown using the Company's proprietary three-dimensional expansion technology and can be administered to patients off-the-shelf, without tissue matching. Pluristem has a strong intellectual property position; a Company-owned and operated GMP-certified manufacturing and research facility; strategic relationships with major research institutions; and a seasoned management team.

**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, Pluristem is using forward-looking statements when it discusses the intended use of proceeds of the Financing from the EIB to support its research and development in the EU to further advance its regenerative cell therapy product candidates, with a special focus on the treatment of complications associated with COVID-19, the belief that its financial resources are expected to fund its operations for the next three years, the creation of jobs and opportunities by Pluristem in the EU, the expected timing of interim data readouts, patient enrollments and the timing of public announcements of its clinical trials, and the timing of enrollment of certain studies, and the expected response from regulators, with respect to its IND application for the use of its PLX cells for the treatment of complications associated with COVID-19. 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; Pluristem may encounter delays or obstacles in launching and/or successfully completing its clinical trials; Pluristem’s products may not be approved by regulatory agencies; Pluristem’s technology may not be validated as it progresses further and its methods may not be accepted by the scientific community; Pluristem 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 Pluristem’s process; Pluristem’s 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; results

of preclinical studies may not correlate with the results of human clinical trials; Pluristem's patents may not be sufficient; Pluristem products may harm recipients; changes in legislation; inability to timely develop and introduce new technologies, products and applications and; loss of market share and pressure on pricing resulting from competition, which could cause Pluristem's actual results or performance 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.

**Contact:**

Dana Rubin

Director of Investor Relations

972-74-7107194

[danar@pluristem.com](mailto:danar@pluristem.com)