



## **Pluristem and Sosei CVC to Establish a New Corporation for the Commercialization of PLX-PAD in Japan**

- *Pluristem and Sosei CVC will establish a new corporation which will pursue the clinical development and commercialization of PLX-PAD in Japan*
- *The first indication to be developed will be Critical Limb Ischemia (CLI)*
- *Japan's regulatory agency has already agreed on the study design of a 75-patient clinical trial in CLI for potential conditional marketing approval under an accelerated pathway*
- *Initial funds of \$11 million will be invested into the new corporation by Sosei RMF1 and partners*

**HAIFA ISRAEL, TOKYO JAPAN December 20, 2016 --** Sosei Corporate Venture Capital Ltd., (Subsidiary of Sosei Group Corporation, a Tokyo Stock Exchange Mothers listed company), and [Pluristem Therapeutics Inc.](#) (NasdaqCM: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, today announced the signing of a binding term sheet for the establishment of a new Japanese corporation (NewCo) for the clinical development and commercialization of Pluristem's PLX-PAD cell therapy product in Japan. Following completion of fund-raising, the parties plan to establish NewCo in Japan. Pluristem will own 35% of NewCo in return for its contribution of a perpetual license to commercialize PLX-PAD for Critical Limb Ischemia (CLI) in Japan. All proprietary rights related to PLX-PAD will be exclusively owned by Pluristem. Sosei CVC's investment fund, Sosei RMF1, together with additional Japanese investors, will raise and invest approximately \$11 million, equivalent to approximately ¥1.3 billion, in return for ownership of 65% of NewCo.

The first indication to be developed by NewCo will be CLI. The design of a 75-patient study of PLX-PAD in CLI was previously agreed upon with Japan's Pharmaceuticals and Medical Devices Agency (PMDA) under an accelerated regulatory pathway for regenerative medicine. This single study may lead to early conditional marketing approval and early reimbursement. Future marketing activities are planned to be undertaken by NewCo. The parties plan to enter into a definitive agreement no later than March 31, 2017.

"We are pleased to partner with Sosei CVC to commercialize PLX-PAD in Japan. The development of our CLI program through the accelerated regulatory pathway could allow a more rapid entrance into the sizeable Japanese market, as has been our strategy," stated Zami Aberman, Pluristem's Chairman and CEO. "Our cooperation with Sosei CVC also creates the potential to develop additional indications in this market, by drawing on our robust portfolio of cell therapy product candidates in development," Mr. Aberman added.

“We are eager to begin the joint development of PLX-PAD in critical limb ischemia with the goal of commercialization, and believe that our cooperation could lead to an efficient and successful entry into Japan’s substantial market,” said Toshimi Miyoshi, Director, Sosei CVC. “The NewCo is expected to be a meaningful investment by Sosei RMF1 into the regenerative medicine space, and will support our goal to stimulate the biotechnology industry in Japan,” Miyoshi concluded.

### **About Japan’s Conditional Time-limited Approval for Regenerative Medicine Products**

Japan’s Act on the Safety of Regenerative Medicine went into effect in November 2014. Its purpose is to facilitate faster commercialization of cellular therapies and other regenerative medicine treatments. Per the Act, these therapies can receive conditional, time-limited approval for marketing, and be eligible for reimbursement, upon proof of safety and a signal of effectiveness but prior to verification of efficacy. Safety and efficacy need to be confirmed via collection of observational data from treated patients after the conditional approval.

### **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 and is entering late-stage trials in several indications. The cell products 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.

### **About Sosei CVC and RMF1**

Sosei Corporate Venture Capital (Sosei CVC) is the corporate venture arm of Sosei Group Corporation, a Tokyo Stock Exchange Mothers listed company. Along with its partners, Sosei CVC currently manages Sosei RMF1, a ¥2 billion fund focusing on investing in companies with innovative regenerative medicine technology.

### **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, we are using forward-looking statements when we discuss the establishment of a Japanese new corporation, our expected holdings in the new corporation and the investment of approximately \$11 million in the new corporation by Sosei RMF1 and additional partners; when we discuss the development and marketing plans of the new corporation; when we discuss PLX-PAD’s potential eligibility for early conditional marketing approval, and for reimbursement, following a single, PMDA-approved clinical trial; when we discuss the parties’ plan to enter into a definitive

agreement and the proposed date of execution of such agreement; when we discuss the potential of the accelerated regulatory pathway to allow us a more rapid entrance into the sizeable Japanese market; and when we discuss the potential of our cooperation with Sosei CVC to develop additional indications in the Japanese market. Further, although Pluristem has signed a binding term sheet, it may not be successful in negotiating definitive documentation by the date expected or at all, and even if successful, the transaction may not be completed if the conditions to closing are not met. 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.

**Contact:**

Karine Kleinhaus, MD, MPH  
Divisional VP, North America  
1-914-512-4109

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

Efrat Kaduri  
Investor and Public Relations Manager  
972-74-7108600

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