



## **Pluristem Pursues Development Strategy in Japan Where New Law Accelerates Path to Market**

**HAIFA, ISRAEL, September 16, 2014** -- [Pluristem Therapeutics Inc.](#) (NasdaqCM: PSTI) TASE: PLTR), a leading developer of placenta-based cell therapy products, announced today it is evaluating strategic opportunities to co-develop and commercialize its PLacental eXpanded (PLX) cell therapies in Japan.

Recent changes in Japan's laws governing regenerative medicine and the approval of stem cell therapies indicate the country may now offer the fastest track to commercialization in the world for regenerative medicine treatments. As part of Pluristem's strategy in Japan, on September 16, 2014, Company executives presented to a group of Japanese pharmaceutical executives in Tokyo, and conducted a series of one-on-one meetings with Japanese companies exploring a potential partnership with Pluristem.

To support its strategy in Japan, Pluristem is working with [The Sage Group](#), a consulting firm specializing in healthcare industry transactions and business strategy, and Sage's partner [Waterfield HealthCom](#), a Japan-based firm managed by Yoshi Mizuta. Mr. Mizuta is a highly experienced pharmaceutical industry executive with more than 40 years in the business of financial healthcare transactions in the Japanese arena.

Japan's government passed a bill in 2013, which goes into effect in November of this year, effectively fast-tracking the approval of stem cell therapies for marketing. According to the law, stem cell regenerative medicine therapies can receive conditional, time-limited approval for marketing, and be eligible for reimbursement, upon proof of safety but prior to verification of efficacy; safety and effectiveness need to be confirmed after the conditional approval.

Waterfield HealthCom's Mr. Mizuta commented, "With its broad portfolio of indications and its commercial scale 3D cell manufacturing capabilities, Pluristem is a very desirable partner for Japanese pharmaceutical companies looking to bring cell therapies to the market in the near term."

"As a result of Japan's favorable new law, cell therapies like Pluristem's PLX cells can receive market approval in Japan upon completion of Phase II trials when good safety and efficacy data is available. This could potentially reduce approval time down to two or three years," Mr. Mizuta concluded.

Pluristem CEO Zami Aberman added, “The opportunity in Japan opens an accelerated path for the global regenerative medicine industry to prove the efficacy of cell therapies in a broad patient population in Japan. Japan has one of the most advanced healthcare systems, and the [second largest healthcare market](#) in the world.”

Pluristem currently has co-development and out-licensing partnership agreements with United Therapeutics (NASDAQ: UTHR) and South-Korea-based CHA Bio&Diosynth (KOSDAQ: CHA).

### **About Pluristem Therapeutics**

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The Company's patented PLX (PLacental eXpanded) cells are a protein delivery platform that releases a cocktail of therapeutic proteins in response to inflammation or ischemia. PLX cells are grown using the Company's proprietary 3D micro-environmental technology and are an "off-the-shelf" product that requires no tissue matching prior to administration.

Pluristem has a strong intellectual property position, Company-owned GMP certified manufacturing and research facilities, strategic relationships with major research institutions and a seasoned management team. For more information visit [www.pluristem.com](http://www.pluristem.com), the content of which is not part of this press release.

### **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 the opportunity in Japan including receiving market approval in Japan for our products upon completion of phase II which could potentially reduce approval time. 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 surgical 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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