



Current Agreements

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Join venture and licensing agreement for new company for commercialization of PLX-PAD cell therapy product

Pluristem Therapeutics
Sosei

Dec 21 2016

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Companies:	Pluristem Therapeutics Sosei
Announcement date:	Dec 21 2016
Deal value, US\$m:	11 : sum of funding

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Details

Announcement date:	Dec 21 2016
Industry sectors:	Biotech Pharmaceutical
Asset type:	Business
Therapy areas:	Cardiovascular
Technology types:	Regenerative medicine » Cell therapy Joint venture
Deal components:	Licensing Spin out
Stages of development:	Preclinical
Geographic focus:	Worldwide

Financials

Deal value, US\$m:	11 : sum of funding
Funding, US\$m:	11 : funding

Termsheet

Sosei Corporate Venture Capital and Pluristem Therapeutics 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.

Press Release

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 and TOKYO, Dec. 21, 2016 (GLOBE NEWSWIRE) -- Sosei Corporate Venture Capital Ltd., (Subsidiary of Sosei Group Corporation, a Tokyo Stock Exchange Mothers listed company), and Pluristem Therapeutics Inc. (Nasdaq: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.

Filing Data

Not available.

Contract

Not available.