2016, Nov., 11th

Company name ReproCELL Inc.
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Announcement on the initiation of a new business from the collaboration and commercialization agreement with Steminent Biotherapeutics Inc. for cell therapy

Today, ReproCELL Inc. ("ReproCELL") has entered into a partnership with Steminent Biotherapeutics Inc. ("Steminent") to develop and commercialize Steminent's allogeneic stem cell therapy product, Stemchymal, in Japan. This announcement is in response to the acceptance of the agreement from the board committee on the even date.

Notice

1. The purpose of this agreement

Based on the terms of this agreement, ReproCELL will gain exclusive rights for the development and commercialization of Stemchymal for treating Spinocerebellar ataxia ("SCA") in Japan. Along with this agreement, ReproCELL will also have the right of first negotiation of the development and commercialization for other indications.

"Act on the Safety on Regenerative Medicine" and a revision to the "Pharmaceutical and Medical device Act" took effect in Japan on November 25th, 2014. This enables acceleration of the development of pharmaceuticals related to regenerative medicine by introducing "Time-limited conditional approval" which allows selling while continuing clinical trials of the pharmaceuticals that have been proved to have safety and probable efficacy in Japan. ReproCELL intends to leverage this new system during the development of Stemchymal and aim early commercialization, while receiving support from Steminent.

This agreement is the first step for ReproCELL to enter into the regenerative medicine industry, for Stemchymal is the first pharmaceutical product for ReproCELL.

2. The details of the new business

ReproCELL plans to develop Stemchymal in Japan as a treatment for SCA. Stemchymal is expected to function as a treatment for SCA which is classified as an intractable disease by the Ministry of Health and Labor Welfare. SCA is a progressive neuro degeneration disease, which is seen especially in the cerebrum, brainstem, and spinal cord, with motor ataxia symptoms such as walking disorders and swallowing difficulties. There are approximately 30,000 patients in Japan, yet the cause of this disease has still not been elucidated.

Moreover, Stemchymal, which was granted Orphan Drug Designation by U.S. FDA, is now in its phase II trial among the all three phases in Taiwan and is also preparing for trials in U.S.

Steminent is a global biopharmaceutical company which spun-off from National Yang Ming University in

Taiwan. The company was granted “New Biopharma Company Status” from the Ministry of Economic Affairs in Taiwan, with cell therapy development pipeline which includes both early stage research and later stage clinical development programs. Steminent has developed their proprietary, needle-to-needle cell technology platform and is now dedicated to the discovery, research, clinical development and commercialization of novel cellular therapeutics for the treatment of unmet and underserved medical needs.

“It is a great pleasure to partner with Steminent to enter into an exclusive agreement on development and commercialization of Stemchymal, which makes excellent use of cutting-edge technologies, for SCA. Under this agreement, we will start clinical development of the product to directly serve patients. We will pull off the development of Stemchymal to help desperate patients.” said Chikafumi Yokoyama, CEO of ReproCELL. “The know-how we gain from this clinical development will naturally contribute to our next business strategy, which is the iPS cell therapy. We will accelerate our business by taking our first step into the regenerative medicine field.”

“Steminent Biotherapeutics is extremely pleased to partner with ReproCELL, one of the most established companies in the rapidly expanding regenerative medicine industry, for the purpose of advancing our stem cell therapeutics in the Japan market,” said Ryan Chang, President. “What’s exciting is that this partnership expands clinical development of our lead stem cell therapeutic into Japan to further advance this novel treatment candidate for patients suffering from spinocerebellar ataxia (“SCA”), a debilitating neurodegenerative disease for which there are currently no effective treatments.”

As part of the initiation of this new business, ReproCELL will be investing approximately US$1M to Steminent as an allocation of new shares to a third party, and will also be paying development milestones which would total approximately US$4M. In addition, royalty payments will be made during commercialization.

ReproCELL will be developing the product with Steminent to meet the Japanese pharmaceutical regulations for approximately 1 year after this agreement, followed by initiating clinical trials in 2017, obtaining Time-limited conditional approval in 2020, and receiving Marketing approval in 2023.

【Definition of words】

・Allogeneic Stem Cells・・・Stem cells harvested from donors and not from the treated patients

・FDA・・・Food and Drug Administration
A regulatory authority specialized in pharmaceuticals and foods

・Orphan Drug・・・Drugs for rare diseases. Upon receipt, special benefits such as development subsidy and prioritized review can be enjoyed.

3. Schedule

（1）	Date of agreement	2016, Nov., 11th
（2）	Date of execution	2016, Nov., 11th

4. Summary of the other party

（1）	Company name	Steminent Biotherapeutics Inc.
（2）	Location	No. 16, WenHu Street, NeiHu Dist., Taipei
（3）	Representative	Ryan Chang, President
（4）	Scope of business	Manufacturing and Selling of Biopharmaceuticals
（5）	Capital	265.3M TWD
（6）	Establishment date	2007, December

（7）	Major shareholder and its share ratio	The CID Group （26.4%） Nuliv Holdings Inc. （17.9%）	
（8）	Former relationship with ReproCELL	Capital	None
		Human resource	None
		Transaction	None
		Applicable to “Related party”	No
（9）	Financial situation in the last 3yrs	Non-disclosure due to non-listed company	

5. Prospect

The impact of this agreement on the financial performance of the business year ending in March 2017 is minimal. However, in an event where events-to-disclose takes place, it will be announced promptly.

For information on financial impacts on the next business year, please refer to the “Announcement on the revision of medium-term management plan”.

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