April 4, 2022
Metcela Inc.

# Metcela acquires Japan Regenerative Medicine Co., Ltd., developing cardiac stem cell-based therapy

*Through this acquisition, Metcela will add an autologous cell product for pediatric congenital heart disease to its pipeline and significantly strengthen its clinical development infrastructure for regenerative medicine products*

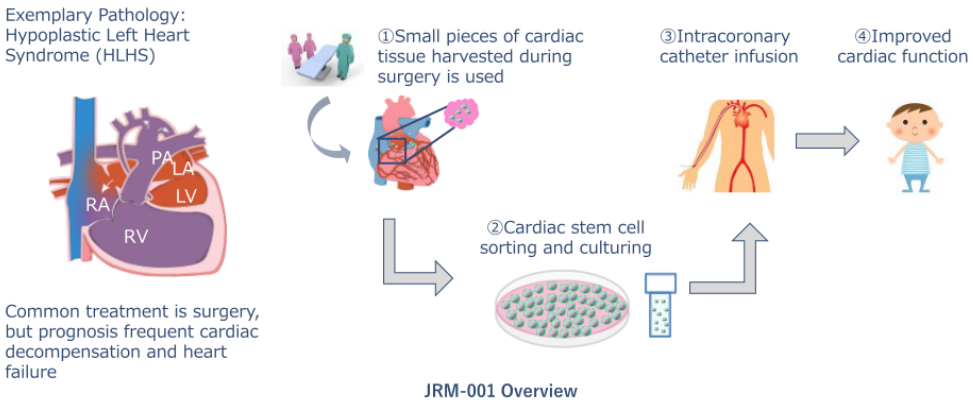
**Kanagawa, Japan- Metcela has acquired Japan Regenerative Medicine Co., Ltd. (“JRM”), a wholly owned subsidiary of Kidswell Bio Co., Ltd. (“Kidswell Bio”) in which Metcela has established a business alliance with just this January. To further strengthen its partnership, Metcela allocated new shares to Kidswell Bio.**


## About JRM

JRM is developing a new cell therapy product, “JRM-001” for serious cardiac diseases, namely pediatric congenital heart disease, using cardiac stem cells ("CSCs"). JRM-001 is targeting single ventricle, which is one of the most common pediatric congenital heart diseases affecting about 400-500 patients annually. Currently JRM-001 is going through Phase III clinical trial in Japan to evaluate the improvement of cardiac function after standard surgical repair of the heart and the team is aiming for speedy approval and commercialization.

Surgery is the common treatment for single ventricle, and although the post-operative survival rate has been improving in recent years, 90% of post-operative patients is said to develop cardiac decompensation or heart failure by the age of 40 and the 25-year survival rate is about 70%, making it a serious disease.

Research results suggesting the safety and efficacy of CSC-based therapy for single ventricle have already been reported with Phase I and Phase II clinical results, where the trials were conducted at Okayama University as clinical research.




JRM-001 Overview

## Aims of this Acquisition

Since founding in 2016, Metcela held "Revolutionizing the way we treat heart failure." as the company's mission and worked on researching and developing a new autologous cell therapy product for heart failure. Metcela's lead asset, MTC001, is a combination product of autologous VCAM-1-positive cardiac fibroblasts ("VCF") and a precision delivery device, and the safety and efficacy has been confirmed in preclinical studies.

To further accelerate the R&D activities, Metcela entered into a business alliance agreement with Kidswell Bio on January 19, 2022, and have been exchanging management resources, knowledge, and technology in the regenerative medicine field. As a result, the two parties have reached an agreement that the best path forward for JRM's future business growth is for Metcela to take the lead in the development of CSCs, as Metcela have accumulated experience and know-how in the development of autologous cell products and have established a well-developed research and development system.

This acquisition will enable Metcela to expand the product development portfolio. Both CSCs, targeting pediatric heart disease, and VCFs, targeting adult chronic heart failure, have many commonalities as they are both autologous cells and delivered via catheter. This is consistent with Metcela's belief that for highly immunoresponsive organ, like the heart, minimally invasive autologous therapy not requiring immunosuppression is the most ideal. By developing these pipelines in an integrated manner, Metcela will be able to bring seamless pipeline development for a wide range of cardiac diseases and, in the future, relish a wide range of synergies in terms of sharing manufacturing know-how and sales systems.

The clinical development team for MTC001 will also be dramatically strengthened by taking over the autologous regenerative medicine clinical development operations expertise that JRM has built up to date for the development of JRM-001. Metcela plans to integrate the organizations of JRM and work in unison to accelerate the development of MTC001 in Japan and overseas, and to complete the clinical trial of JRM-001.

As part of this acquisition, Metcela has agreed to pay Kidswell Bio a certain royalty based on JRM's sales of regenerative medicine products, and Kidswell Bio's support of JRM will continue.

## Strengthening Collaboration through the Issuance of Shares to Kidswell Bio

To further deepen the business alliance already placed, Metcela issued new shares to Kidswell Bio by a third-party allotment. Metcela will further expand discussions on strengthening collaboration by utilizing the know-hows of the two companies and applying Kidswell Bio's experience on establishing a master cell bank for stem cells from human exfoliated deciduous teeth (SHED) to VCF and CSC businesses.

## Recent Financing to Accelerate Development of MTC001

Also today, Metcela has announced the procurement of additional funds from Osaka University Venture Capital Co., Ltd. ("OUVC") and Tohoku University Venture Partners Co., Ltd. ("THVP") to accelerate the development of MTC001. For details of this financing, please refer to the press release titled "Metcela Raises Funds from Two University VC Firms".

## JRM Overview

Company Name: Japan Regenerative Medicine Co., Ltd.
Established: October 2013
Business Activities: Research and development of regenerative medicine technologies and products and cellular medicines

## About Metcela

Metcela Inc., established in 2016, is a clinical-stage biotechnology startup pioneering the research and development of fibroblast and stem cell-based therapy for chronic diseases that currently have limited therapeutic options. MTC001 is a combination product of autologous cardiac cells (VCAM-1-positive Cardiac Fibroblast, VCF) and a novel catheter delivery system targeting chronic heart failure patients. MTC001 offers two major advantages over other cell therapies: (1) the therapeutic cells are autologous (patient-derived) and homologous (tissue-specific i.e. cardiac-derived), which is most suitable for the heart, as it is a highly immunogenic organ, and (2) the minimally invasive catheter system is equipped with a highly functional injection needle specifically designed for this therapy to achieve reliable and safe administration of the cells.