

Info Sheet for Technical description

No. 0004

Organization

* Mandatory fields

Name of Organization*	iHeart Japan corporation		
Address, City, States, Zip, Country*	280, Tenjinyamacho, Kyoto-shi Nakagyo-ku, Kyoto, 604-8221, Japan		
URL	http://iheartjapan.jp/		
Brief Descriptions of Organization* (Approx. 100 words)	Developing allogeneic regenerative medicinal products derived from iPS cells, and selling research tools for cardiotoxicity and efficacy. The base technology was invented by Prof. Jun Yamashita of Kyoto Univ. Center of iPSC Research and Application at the time.iHeart Japan Corporation were founded in 2013 and then acquired core patents. We established our own cell processing facility (CPF) in Kyoto, in which we manufacture our products under the regulation of Japan called as Good Gene, Cellular, and Tissue-based Products Manufacturing Practice (GCTP) compliant system. We are developing a regenerative medicinal product for heart failure.		
Contact address	Name*	Osamu Wada	
	Department* / Position	Operation Dept. / Business Development Team Leader	
	E-mail* / TEL	osamu.wada@iheartjapan.jp	

What kind of technology do you want to offer? *

- ☒ **A.** Clinical Development Pipelines → Please see **Sheet [A]**
- ☐ **B.** Regenerative Medicine-related Consumables / Instruments / Materials / CDMO Services etc. → Please see **Sheet [B]**
- ☐ **C.** Platform Technologies(*) that are not included in the above (Group B) → Please see **Sheet [C]**
- * Peripheral technologies that contribute to a significant improvement in productivity throughout the value chain of pharmaceuticals, from research and development to manufacturing and ultimately market launch.

If you agree to the following, please check "Yes" below. *

The technologies introduced in this 'Info Sheet' are in the public domain, as they have been published in research papers or have related patent applications.

☒ Yes

Do you have any collaborations/partnerships with pharmaceutical companies?

- ☐ Yes
- ☒ No

If you have already received funding from VCs or other sources, up to which stage has the investment round progressed?

- ☐ Angel / Seed (including AMED/JST grants)
- ☐ Series A
- ☐ Series B
- ☒ Series C
- ☐ Series D or further advanced stages

Do you agree to leave your presentation materials at FIRM hands and entrust us to make use of them for the purpose of promoting your partnering opportunities? *

Options*	Comments
☐ Yes	
☒ No	

Filled in by*

Date*

Osamu Wada
1/8/2025

Sheet [A] Clinical Development Pipelines**Info Sheet for Technical overview**

No. A-0004

* Mandatoty fields

Title***IHJ-301****Development Phase***

- | | | |
|--|---|---|
| ☐ Basic Research | ☐ Drug Discovery | ☐ Pre-Clinical |
| ☒ Clinical Trial (Phase I) | ☒ Clinical Trial (Phase II) | ☐ Clinical Trial (Phase III) |
| ☐ Review | ☐ Others | |

Diesease Area*

- | | | |
|--|---|--|
| ☐ Cancer | ☐ Central nervous system | ☐ Ophthalmology |
| ☐ Musculoskeletal | ☐ Endocrine / Metabolism | ☒ Cardiovascular |
| ☐ Urogenital | ☐ Digestive organ | ☐ Blood |
| ☐ Infection | ☐ Dermatology | ☐ Immunity |
| ☐ Otolaryngology | ☐ Respiratory | ☐ Others |

Description*

The product consists of cardiac cell sheets and biomaterials. We have the technology to efficiently produce cardiomyocytes and vascular endothelial cells from iPS cells. Furthermore, we also have a cell sheet lamination technology using gelatin hydrogel microspheres, which enables us to manufacture multi-layered cardiac cell sheet. We named the product as IHJ-301.

IHJ-301 showed extremely high efficacy for myocardial infarction model of pig. In that case, cardiac functions of pigs were recovered to the equivalent level to those of healthy pigs. We believe that the gelatin hydrogel microspheres contribute to the long-term survival of IHJ-301 implanted on the surface of the heart of pig. During such long-term survival, IHJ-301 secreted large amount of various cytokines and extracellular vesicles, and repaired the heart tissue of disease model pig. That is the competitive advantage of IHJ-301.

Furthermore, IHJ-301 showed great effectiveness for dilated cardiomyopathy model of hamster, having genetic mutation of gamma sarcoglycan.

We have completed pre-clinical studies of IHJ-301 and **enrolled our first patient in the clinical trial of IHJ-301 in 2025.**

Filled in by*

Osamu Wada

Date*

1/8/2025