## **Info Sheet for Technical description**

No. 0004

| Organization | * Mandatoty field |
|--------------|-------------------|
|              |                   |

| 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. |  |  |
|   | Name*  | Osamu Wada   |  |
| Contact address   | Department* / Position   | Operation Dept. / Business Development Team Leader |  |
|   | E-mail* / TEL  | osamu.wada@iheartjapan.jp                          |  |

| Addicss,  | city, States, Zip, Country   | 200, Tenjinyamacho, kyoto shi Nakagyo ka, kyot  | 0, 00 1 0221, 3apan                                |  |  |
|---|--|---|--|--|--|
| 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 unde 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. |  |  |  |
|   |  | Name*   | Osamu Wada   |  |  |
| Contact a   | nddress  | Department* / Position  | Operation Dept. / Business Development Team Leader |  |  |
|   |  | E-mail* / TEL   | osamu.wada@iheartjapan.jp                          |  |  |
|   |  |   |  |  |  |
| What kin  | d of technology do you want to offer?  | *   |  |  |  |
| ✓   | A. Clinical Development Pipelines  |   | → Please see <b>Sheet [A]</b>                      |  |  |
|   | B. Regenerative Medicine-related Consumables   | / Instruments / Materials / CDMO Servicies etc.   | → Please see <b>Sheet [B]</b>                      |  |  |
|   | C. Platform Technologies(*) that are not include   | ed in the above (Group B)   | → Please see <b>Sheet</b> [C]                      |  |  |
|   | * Peripheral technologies that contribute to a si<br>the value chain of pharmaceuticals, from resear<br>ultimately market launch.  | gnificant improvement in productivity throughout<br>rch and development to manufacturing and  |  |  |  |
|   | ologies introduced in this 'Info Sheet' are in<br>in research papers or have related patent ap<br>Yes  |   |  |  |  |
| V.  | Tes  |   |  |  |  |
| Do you h  | ave any collaborations/partnerships w  | ith pharmaceutical companies?   |  |  |  |
|   | Yes  |   |  |  |  |
| $\checkmark$  | No   |   |  |  |  |
|   | ve already received funding from VCs on the control of the control | or other sources, up to which stage   |  |  |  |
|   | Angel / Seed (including AMED/JST grants)   |   |  |  |  |
|   | Series A   |   |  |  |  |
|   | Series B   |   |  |  |  |
| ✓   | Series C   |   |  |  |  |
|   | Series D or further advenced stages  |   |  |  |  |
|   | gree to leave your presentation materi<br>e of them for the purpose of promoting   |   |  |  |  |
|   | Options*   |   | Comments   |  |  |
|   | Yes  |   |  |  |  |
| i   |  | Í   |  |  |  |

|   | Options* | Comments |
|---|----------|----------|
|   | Yes      |          |
| V | No       |          |

| Filled in by* | Osamu Wada |
|---------------|------------|
| Date*         | 5/9/2024   |

## **Info Sheet for Technical overview**

No. 0004

| Title*   |                          |  |                           |          | * Mandatoty fields         |
|--|--------------------------|--|---------------------------|----------|----------------------------|
|  |                          |  | <u>IHJ-301</u>            |          |                            |
| Developr   | nent Phase*              |  |                           |          |                            |
|  | Basic Research           |  | Drug Discovery            | <b>V</b> | 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    | V        | Cardiovascular             |
|  | Urogenital               |  | Digestive organ           |          | Blood                      |
|  | Infection                |  | Dermatology               |          | Immunity                   |
|  | Otolaryngology           |  | Respiratory               |          | Others                     |
| Descripti  | on*                      |  |                           |          |                            |
| 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 we can initiate the clinical trial of IHJ-301 within 2024. |                          |  |                           |          |                            |
|  |                          |  |                           |          |                            |
|  | Filled in by*            |  | Osam                      | u Wada   |                            |
|  | Date* 5/9/2024           |  |                           |          |                            |