

March 2, 2020

Cuorips Inc.

Cuorips Started Construction of Cell Culture Processing Facility for Commercial Production

Tokyo, Japan (March 2, 2020) - Cuorips Inc. (Headquarters: Chuo-ku, Tokyo; President: Shoji Hirashima) today announced the start of construction of a labo-integrated cell culture processing facility (called "CLiC-1": Cuorips Labo-integrated Cell Processing Facility for Advanced Therapy-1st), which is designed for commercial production of cell therapy products, in Minoh City, Osaka.

We currently participate in collaborative research and development of allogeneic iPS cell-derived cardiomyocyte sheets¹⁾ for severe heart failure through a joint research laboratory established at the Graduate School of Medicine, Osaka University, and will produce and supply the products using this facility for clinical trials and commercial use in the future. We are also planning to provide contract cell culture processing services, supported by our flexible but highly specialized technology, taking advantage of the unique design, based on an unprecedented, novel concept, of this facility, and utilizing our strengths in cell differentiation/induction technology and our ability in process development.

The design concept of this facility is as follows.

1. A one-stop manufacturing facility with an integrated laboratory, allowing the development of efficient and highly productive production processes, and actual production
2. Facility operation that achieves efficient and stable mass culturing based on an advanced local air flow control technology ("Air Barrier Booth"²⁾ manufactured by DAI-DAN Co., Ltd.).
3. Cross-contamination prevention design for multiple projects

DAI-DAN Co., Ltd. (Head office: Nishi-ku, Osaka; President: Ichiro Fujisawa) undertakes the design and construction of the facility, which is scheduled to start operations in early summer 2020. With the establishment of this facility, Cuorips will further accelerate the commercialization of allogeneic iPS-derived cardiomyocyte sheets while contributing to the creation of other innovative cell therapy products through the culturing and processing of various cell products.

We will introduce the details of the design and features applied for this facility at upcoming scientific meetings, and the following two presentations, planned jointly with DAI-DAN Co., Ltd., were accepted by the 19th Congress of the Japanese Society for Regenerative Medicine (The meeting detail is under discussion by the congress office).

Presentation 1: Oral Session No. O-02-1: Validation study of a new CPF design concept that enables efficient manufacture of regenerative medicines with mass culture

Presentation 2: Oral Session No. O-23-3: Risk analysis in manufacturing facilities for regenerative medicines based on a new design concept involving a semi-open airflow control booth

(For reference)

Cuorips Inc.

Cuorips Inc. is a start-up company that was established in March 2017, based on technology and research results of Osaka University, for the purpose of development and commercialization of iPS cell-derived cardiomyocyte sheets.

Cuorips is developing the technology on production process of iPS cell-derived cardiomyocyte sheets, to establish more efficient one, and to obtain NDA approval as a world 1st regenerative medicines for severe Heart Failure.

1: iPS cell-derived cardiomyocyte sheet

This is an allogeneic cell therapeutic product mainly composed of cardiomyocytes (iPS myocardium), differentiated from human iPS cells that are processed into a sheet that can be transplanted into the surface of patient's heart. Therapeutic effects such as improvement of heart function and recovery of heart failure can be expected in the patients with severe heart failure such have no treatment option besides heart transplantation or artificial heart implantation.

2: Air barrier booth

This is a semi-open clean booth for aseptic processing of regenerative medicines, developed by DAI-DAN Co., Ltd., and its major feature is the absence of a door at the opening. One-way airflow is created from the opening to the outside of the booth, preventing foreign matters from entering the booth despite a doorless structure.

[Inquiries regarding this matter]

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