

September 23, 2020

Cuorips Inc.

Cuorips officially commenced operations at its new state-of-the-art commercial cell processing facility

Tokyo, Japan (September 23, 2020) - Cuorips Inc. (Headquarters: Chuo-ku, Tokyo; President: Takayuki Kusanagi) today announced opening of its new commercial cell processing facility (Cuorips Labo-integrated Cell Processing Facility for Advanced Therapy-1st, called "CLiC-1") in Minoh City, Osaka.

"CLiC-1", being specially deigned based on Cuorips' original concept, is capable for stable and efficient manufacture of iPS cell-derived cardiomyocyte patch at reasonable cost. First production at this new facility will be clinical supply for the on-going investigator-initiated clinical trial, conducted by Osaka University Hospital for patients with severe heart failure. "CLiC-1" will then take a role of commercial manufacturing after launch, which is estimated in 2023.

In addition, "CLiC-1" is a laboratory-integrated manufacturing facility, which makes one-stop services available, from process development to manufacturing and QA, for regenerative medicine products as well as cell processing products, and will provide CDMO services for various cell processing products.

The design concept of "CLiC-1" 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") manufactured by DAI-DAN Co., Ltd.
3. Cross-contamination prevention design for multiple projects.

Cuorips will further accelerate the commercialization of iPS cell-derived cardiomyocyte patch product through operating "CLiC-1", and will contribute to the creation of innovative cell therapy products.

(For reference)

1: Outline of the facility

【Name】 “CLiC-1”: Cuorips Labo-integrated Cell Processing Facility for Advanced Therapy-1st

【Address】 Cuorips Senri R&D Center, 3-4-17, Senba Higashi, Minoh City, Osaka

【Floor Area】 Approx. 1,000 m²

【Production Room】 3 production rooms

(iPS cell-derived Product Manufacturing Room X 1, other production room X 2)



iPS cell-derived Product Manufacturing Room

2: 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 patch.

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

3 : iPS cell-derived cardiomyocyte patch

An allogeneic cell therapeutic product mainly composed of cardiomyocytes (iPS myocardium), differentiated from human iPS cells that are processed into a patch 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 options.

4: Air Barrier Booth

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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