



September 26, 2023

Dear Members of the Press,

iPark Institute Co., Ltd.

iPark Institute Co., Ltd. and Eleven Industry Partners Collaboratively Translate and Release "A-CELL", a Key Cellular Drug Manufacturing Document

 The participating companies include AGC Inc., Chugai Pharmaceutical Co., Ltd., Global Life Sciences Technologies Japan K.K. (Cytiva), Orizuru Therapeutics, Inc., Nihon Pall Ltd., Hitachi Global Life Solutions, Inc., Mitsubishi Corporation, PeptiGrowth Inc., Takeda Pharmaceutical Company Limited, Terumo BCT Japan, Inc., and Thermo Fisher Scientific Japan Group (*1).

iPark Institute Co., Ltd. (headquartered in Fujisawa, Kanagawa, Japan; CEO Toshio Fujimoto; hereinafter "iPark Institute") announced today its collaboration with industry leaders such as AGC Inc., Chugai Pharmaceutical Co., Ltd., Global Life Sciences Technologies Japan K.K. (Cytiva), Orizuru Therapeutics, Inc., Nihon Pall Ltd., Hitachi Global Life Solutions, Inc., Mitsubishi Corporation, PeptiGrowth Inc., Takeda Pharmaceutical Company Limited, Terumo BCT Japan, Inc., and Thermo Fisher Scientific Japan Group, in translating and publishing a Japanese version of the cellular drug manufacturing guide "A-CELL" (available at: https://alliancerm.org/manufacturing/a-cell-2022/). This initiative aims to enhance knowledge and address challenges in next-generation therapeutics.

The original "A-CELL" document, released in July 2022 by the Alliance for Regenerative Medicine (ARM) and The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), compiles best practices for CMC (*2) in cell medicine manufacturing. The Japanese translation will serve as a vital resource for researchers and manufacturing personnel, offering guidance on cellular drug production, quality control, regulations, and related materials.

During this collaborative project, the participating companies not only divided the

translation work but also organized 13 study sessions. These sessions facilitated discussions on chapter contents, interpretations, and issue awareness. Key discussion points included the need for human resource development, the challenges and significance of knowledge sharing in cellular drug production, and the necessity of continually updating knowledge about auxiliary materials in the field. iPark Institute views these discussions and shared insights as crucial for building an ecosystem for future therapies and plans to continue such initiatives.

The Japanese version of "A-CELL" can be accessed at https://www.shonan-ipark.com/initiative/a-cell/.

Toshio Fujimoto, CEO of iPark Institute, highlighted the challenges in cellular medicine, especially in large-scale production and commercialization (*3). He emphasized Shonan iPark's commitment to advancing next-generation therapy R&D through "facility, equipment, and technical support", "clinical research connections", and "human resource development and support". He expressed hope that the A-CELL translation and study sessions, jointly conducted by various companies, will not only enhance participant knowledge but also foster industry-wide R&D capabilities through information exchange and discussion.

- *1. Companies listed in alphabetical order; certain exceptions apply.
- *2. "Chemistry, Manufacturing and Control" focusing on design and product quality.
- *3. Excerpt from "A-CELL" introduction (Japanese translation).

About iPark Institute Co., Ltd.

Founded in April 2023, iPark Institute Co., Ltd. began its journey with significant backing from Sangyo Fund Investment Corporation, Takeda Pharmaceutical Company Limited, and Mitsubishi Corporation as principal shareholders. Our mission extends beyond the operational and managerial aspects of the facility. We are deeply committed to fostering innovation, facilitating technological exchange, and encouraging research collaborations. These efforts are pivotal in nurturing and invigorating the life science ecosystem. Discover more about our company here.

About Shonan Health Innovation Park (Shonan iPark)

Shonan iPark, established in April 2018, represents Japan's pioneering science park initiative led by a pharmaceutical company. This endeavor began when Takeda Pharmaceutical Company opened its research lab to external collaborations. Now under

the independent management of iPark Institute Co., Ltd., Shonan iPark is dedicated to becoming a hub where diverse industries, including government and academia, converge to propel health innovation forward. Today, the park hosts not only pharmaceutical entities but also organizations specializing in next-generation medicine, cellular agriculture, artificial intelligence, and government sectors. This vibrant ecosystem comprises approximately 160 companies and over 2,000 individuals (as of September 2023).

Official website: https://www.shonan-ipark.com/

For the latest information on tenants and member companies at Shonan iPark, click here.

Stay connected through our official social media accounts: YouTube / Facebook / Twitter / LinkedIn

For Media Inquiries:

iPark Institute Co., Ltd. Attn: Takizawa, Hibino

Email: iPi.Com@shonan-ipark.com