

September 27, 2022

Showa Denko Materials Co., Ltd.

Kidswell Bio Corporation

## **Showa Denko Materials and Kidswell Bio Enter into an Agreement for Process Development and Clinical Manufacturing of Cell Therapy Products**

Showa Denko Materials Co., Ltd. (Head office: Chiyoda-ku, Tokyo; President and CEO: Hidehito Takahashi; hereinafter “Showa Denko Materials”) and Kidswell Bio Corporation (Head office: Chuo-ku, Tokyo; President and CEO: Masaharu Tani; hereinafter “Kidswell Bio”) entered into an agreement to enable process development as well as clinical manufacturing of cell therapy products<sup>\*1</sup> utilizing the advantage of SHED<sup>\*2</sup> (Stem cells from Human Exfoliated Deciduous teeth) which is under development by Kidswell Bio. Under the terms of agreement, Minaris Regenerative Medicine Co., Ltd. (Head office: Yokohama-shi, Kanagawa; President and CEO: Hiroto Bando), a subsidiary of Showa Denko Materials, engages to provide service regarding process development and aim for clinical manufacturing of cell therapy products by the end of 2024. Kidswell Bio intends to initiate clinical trials in cooperation with its partner pharmaceutical companies or partner medical institutions.

With biosimilar<sup>\*3</sup> business as its business foundation, Kidswell Bio is accelerating its R&D activities to develop cell therapy products, aiming to create new pharmaceuticals and therapeutics for pediatric diseases in addition to intractable and rare diseases. SHED, which are dental pulp stem cells derived from neural crest cells,<sup>\*4</sup> is expected to be applied to disease of nervous and musculoskeletal system. Through in-house and collaborative researches, Kidswell Bio has been collecting data which indicate effectiveness of SHED for spinal cord injury, cerebral palsy, refractory fracture, etc. In addition, Kidswell Bio is engaged in research for the creation of designer cells,<sup>\*5</sup> next-generation cell therapies that further enhances therapeutic efficacy by combining various technologies and devices with SHED. Under this agreement, the SHED Master Cell Bank (hereinafter “MCB”) established by Kidswell Bio will be utilized for process development and clinical manufacturing of cell therapy products. The SHED MCB is a cell bank to be used as original seed cells for the manufacturing of SHED-derived cell therapy products. Kidswell Bio will promote the development of medical products utilizing the SHED MCB to manufacture not only cell therapy products but also SHED-derived exosome<sup>\*6</sup> products and new treatment methods by combining SHED with gene therapy. It is an important business basis indispensable for the stable supply of new medicines and therapies.

Showa Denko Materials owns Minaris Regenerative Medicine Group (hereinafter “Minaris”),

which is a leading global contract development and manufacturing organization (CDMO) for regenerative medicine products. Minaris has facilities located in Japan, the United States, and Europe, and offers clinical and commercial manufacturing services in compliance with Good Gene, Cellular, and Tissue-based Products Manufacturing Practice (GCTP) of Japan, Current Good Manufacturing Practice (cGMP) of the United States, and Good Manufacturing Practice (GMP) of Europe. Furthermore, Minaris has established a technology for cell expansion using 3D bioreactors which enable manufacturing cost reduction and quality improvement applicable to both adherent and suspension cells.

Minaris' experience in manufacturing regenerative medicine products, its technology for utilizing 3D bioreactors, and its global operations were highly evaluated and led to the conclusion of this agreement.

#### ■ About Kidswell Bio

Kidswell Bio Corporation, with the corporate philosophy of “Biotech Engineering Company, Striving for Value Creation, – For Comprehensive Healthcare System for Children as well as Families and Society –,” operates cell therapy (regenerative medicine) business, biosimilar business, and new biologics business. Kidswell Bio conducts research and development activities on a day-to-day basis to provide innovative pharmaceuticals and therapeutics for patients suffering from diseases, especially children, at an early stage and to contribute to the realization of a society where everybody can live a happy and bright life. For more details, please refer to the website of the company.

Kidswell Bio Corporation: <https://www.kidswellbio.com/en/>

#### ■ About the Showa Denko Group

The Showa Denko Group is a group of chemical companies that produce and sell products related to semiconductor and electronic materials, mobility, innovation enabling materials, chemicals, etc. In 2020, Showa Denko Materials Co., Ltd. (former Hitachi Chemical Company, Ltd.) joined the Group and, as a result, the Group's net sales in 2021 exceeded 1.4 trillion yen. The Group conducts business activities globally through operations of production and sales bases located in 26 countries and regions.

The Group plans to change the Group's common company name into “Resonac” in January 2023,\*<sup>7</sup> and will realize its purpose, “Change society through the power of chemistry,” through the Group's business activities. For detail, please refer to websites of member companies of the Group.

Showa Denko K.K.: <https://www.sdk.co.jp/english/>

Showa Denko Materials Co., Ltd.: <https://www.mc.showadenko.com/english/>

## ■ About Minaris

Minaris is a global contract development and manufacturing organization (CDMO) for cell and gene therapies. Minaris offers clients clinical and commercial manufacturing services, development solutions, and technologies. Minaris is a pioneer in the field with more than 20 years' experience providing outstanding quality and reliability. Minaris' facilities in North America, Europe, and Asia allow the company to supply patients worldwide with life-changing therapies. Minaris Regenerative Medicine Co., Ltd. is wholly owned by Showa Denko Materials Co., Ltd. For detail, please refer to the website of Minaris.

Minaris Regenerative Medicine: <https://www.rm.minaris.com/en/>

- \*1 Regenerative medicine products: These are products made by processing human cells through cell culturing and other means for the treatment and prevention of diseases.
- \*2 Stem cells from human exfoliated deciduous teeth: Stem cells gathered from the pulp tissue inside deciduous teeth and have the ability to differentiate into bone and nerve cells. Because the donor and the cells are young in age, they have higher proliferation potential than stem cells derived from other tissues. They also have high secretional capacity for various growth factors (especially neurotrophic factor).
- \*3 Biosimilar: Biopharmaceuticals (pharmaceuticals manufactured by applying technologies such as genetic recombination and cell culture) that are manufactured and sold after the patent has expired. It has similar quality, efficacy, and safety to prior biopharmaceuticals.
- \*4 Neural crest: This is a part of ectoderm that forms during the development stages of the spinal cord. Neural crest cells differentiate into diverse cell types, including neurons of various peripheral nervous systems, Schwann cells, melanocytes, skin pigment cells, chromaffin cells such as adrenal medullae, smooth muscle of the heart, facial bone and cartilage, corneas, irises, and dental pulp.
- \*5 Designer cells: Designer cells are cellular medicines which have new functions added to those of existing cellular medicines, and are aimed at giving cellular medicines higher effectiveness and enhanced directivity to reach the disease site. Designer cells are watched as next-generation cellular medicines that treat diseases hard to be cured completely.
- \*6 Exosome: This is a nanoparticle secreted from a cell (extracellular vesicle).
- \*7 This change is subject to adoption of relevant resolutions at the extraordinary general meeting of shareholders to be held on September 29, 2022.