S-Quatre and Mochida Sign Agreement to jointly develop Stem cells from human exfoliated deciduous teeth (SHED) based treatment for Pediatric Cerebral Palsy and Traumatic Brain Injury

S-Quatre Corporation ("S-Quatre") and Mochda Pharmaceutical Co., Ltd ("Mochida") are pleased to announce that they have signed amendment to their existing joint business development agreement ("the Agreement"). This new amendment expands their collaboration to include the development and commercialization of cell therapy (regenerative medicine) products using stem cells from human exfoliated deciduous teeth (SHED) for Pediatric Cerebral Palsy (CP) and Traumatic Brain Injury (TBI) in Japan.

Since entering the cell therapy business in 2019, Kidswell Bio Corporation and S-Quatre have been working to elucidate and verify the characteristics and therapeutic potential of SHED through our internal research and joint research with academic institutions, aiming to bring SHED-based regenerative medicine products into clinical use. Among various potential indications, we have prioritized research and development related to CP as a disease for which treatment effects by SHED can be expected due to promising research outcomes. At present, clinical research led by Nagoya University, our joint research partner, and preparations for the application for corporate clinical trials by the end of fiscal year 2025 are progressing smoothly. The clinical development of SHED for CP is advancing steadily towards the next stage.

Given these progresses, S-Quatre and Mochida, which is engaged in the development of new modalities including regenerative medicine while also addressing diverse medical needs, have agreed to share the potential of practical application of SHED and to jointly pursue development and commercialization. Going forward, they will work together to obtain manufacturing and marketing approval in Japan for the new treatment for CP, which currently no standard treatment. In addition, they will also collaborate on research and development for TBI as part of efforts to expand the range of indications. In addition, S-Quatre will continue to independently discuss with potential partners the overseas development of CP and TBI, etc.

The Agreement is an amendment to the existing joint business development agreement disclosed in the "Announcement of the Conclusion of a Joint Business Development Agreement with Mochida Pharmaceutical Co. Ltd. for Regenerative Medicine Products for Rare and Intractable Diseases in the Gastrointestinal Field, Such as Enteric Ganglion Cell Hypoplasia" ("Existing Agreement") dated 23 March 2020. Under the amended terms, CP and TBI have been added to the Existing Agreement as additional target indications of the regenerative medicine products using SHED to be jointly developed and commercialized by S-Quatre and Mochida.

Under the Agreement, Mochida will be primarily responsible for clinical trials, regulatory submissions, distribution and sales, and post-marketing safety information surveys, while S-Quatre will be primarily responsible for manufacturing and non-clinical studies.

Upon completion of the Agreement, S-Quatre will receive an upfront payment from Mochida, as well as milestone payments based on progress in Japan for CP and TBI, and revenues from the supply of SHED-based regenerative medicine products.

As stated in the "Notice regarding one-time gains and expenses and revision of consolidated financial forecast, the upward revision is made based on the impact of the upfront payment under the agreement and the strong sales in our biosimilar business. Please refer to that announcement for more details.

We will provide further updates as necessary regarding the progress of this collaboration.

Profile of Mochida

- (1) Corporate Name: Mochida Pharmaceutical Co., Ltd.
- (2) Address: 7, Yotsuya 1-chome, Shinjuku-ku, Tokyo 160-8515, Japan
- (3) Representative: Naoyuki Mochida, President
- (4) Main Business: Sale, import and export of pharmaceuticals, etc.
- (5) Paid-in Capital: JPY 2,229 million
- (6) Founded: April 16, 1913

Website: https://www.mochida.co.jp/english/

About S-Quatre:

S-Quatre Corporation is committed to developing and providing cell-based therapeutics for rare and intractable diseases by leveraging its proprietary platform for the stable supply of stem cells from human exfoliated deciduous teeth (SHED). The company strives to deliver innovative treatments and therapies to patients suffering from diseases, injuries, and disabilities, particularly children, with the vision of fostering a society where they can live bright and fulfilling lives. For more information, please visit our website.

https://www.kidswellbio.com/en/s-quatre/

Notes:

SHED: Stem cells that are isolated and cultured from the pulp of baby teeth and are considered to be close to nerve cells in terms of embryology. SQ-SHED, which is manufactured using S-Quatre's proprietary production method, exhibits a higher proliferation capacity compared to conventionally produced SHED or stem cells from other tissue sources, and is characterized by its ability to produce a greater amount of protein factors that promote nerve growth and angiogenesis.

Cerebral Palsy: A condition in which the brain is damaged due to hypoxia or inflammation that occurs before or after birth, resulting in lifelong impairment of posture and motor function. While hypothermia therapy is sometimes administered immediately after birth, there is no established treatment for improving motor impairment in childhood once the symptoms have manifested, and the development of new treatments is urgently needed. The number of cases is estimated to be about 2,000 per year in Japan and about 90,000 per year worldwide (data from Global Data).

Traumatic Brain Injury: A condition in which the brain is damaged as a result of a severe blow to the head, such as from a traffic accident or a fall. It can cause motor, sensory, and memory impairment, etc., and in particular, for patients with severe cases, patients may experience long-term difficulties in daily and social life, so there is a need for the development of new treatment methods. The number of cases that occur* is said to be approximately 270,000 per year in Japan and around 6.6 million per year worldwide, and 10-30% of these cases are considered to be moderate or severe (WHO report in *J Rehabil Med.* 2004).