Notice of Patent Acquisition for R-SAT®, a Distribution Management and Administration Schedule Support System for Regenerative Medicine Products, Jointly Developed with Suzuken Co., Ltd.

Tokyo, Japan – May 9, 2022 - SanBio Co., Ltd. (headquarters: Chuo-ku, Tokyo, Representative Director and President: Keita Mori) hereby announces that it has jointly developed and acquired a patent for R-SAT®, a distribution management and administration schedule support system for regenerative medicine products, with Suzuken Co., Ltd. (headquarters: Higashi-ku, Nagoya, Japan, President and CEO: Shigeru Asano).

SanBio and Suzuken have entered into a basic transaction agreement for the commercial distribution relating to the sale and purchase of regenerative medicine product SB623 after launch. SanBio Group (SanBio Co., Ltd. and its subsidiaries SanBio, Inc. and SanBio Asia Pte. Ltd.) had filed for marketing approval of SB623 as a treatment for chronic motor deficit from traumatic brain injury (TBI) with the Japanese Ministry of Health, Labour and Welfare in March 2022. R-SAT is expected to be used in the full range of schedule management processes from production and distribution to post-dose follow-up after the launch of SB623. (Reference: Distribution Management and Administration Schedule Support of Regenerative Medicine Products Using R-SAT®)

R-SAT® is used for the central management of information from registration of patients who receive regenerative medicine products, for which strict quality control is required, to transportation, delivery, administration, and post-dose follow-up. Information managed on this system can be shared between relevant parties, including pharmaceutical companies, manufacturers, logistics companies, and medical institutions. This system will provide a platform for medical institutions to use regenerative medicine products with greater safety and security.

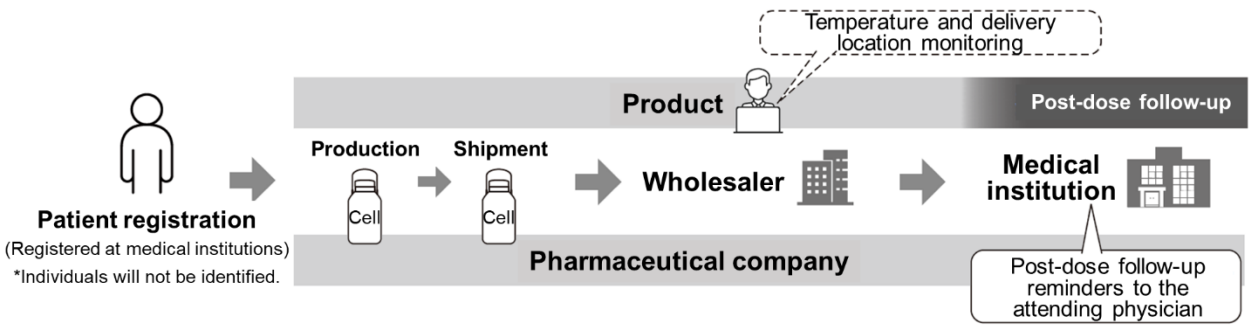
Summary of patent acquired:
Management system and method for regenerative medicine products (Patent No.7061762)
Management system for regenerative medicine products that enables more reliable quality assurance and accurate control in manufacturing and distribution processes

Date of patent acquisition:
April 21, 2022

Reference:

Distribution Management and Administration Schedule Support of Regenerative Medicine Products Using R-SAT®

Image



About R-SAT®

R-SAT®, which is an acronym for Regenerative Medicine, Safety, Accuracy, and Traceability, is a distribution management and administration schedule support system for regenerative medicine products. The system is used for the central management of information from registration of patients who receive regenerative medicine products to transportation, delivery, administration, and post-dose follow-up. Information managed on the system can be shared between relevant parties, including pharmaceutical companies, manufacturers, logistics companies, and medical institutions.

The system will be operated as follows. First, the attending physician will register a patient ID on a dedicated website and enter the administration schedule of the regenerative medicine product. Next, the manufacturer will use this information to ship the product. Then, the logistics operator will manage the product with temperature loggers and GPS and deliver the product to the medical institution while ensuring traceability. Lastly, the medical institution will administer the product to the patient and can also use the system to manage post-dose follow-ups. All of the information in these processes can be shared via the cloud between all relevant parties.

About SB623

SB623 (INN: vandefitemcel) is a human (allogeneic) bone marrow-derived modified mesenchymal stem cell that is produced by modifying and culturing mesenchymal stem cells derived from the bone marrow aspirate of healthy adults. Implantation of SB623 cells into injured nerve tissues in the brain is expected to trigger the brain's natural regenerative ability to restore lost functions. SB623 is currently being investigated for the treatment of several conditions including chronic neurological motor deficit resulting from traumatic brain injury and ischemic stroke.

About Traumatic Brain Injury

Traumatic brain injury (TBI) is one of the leading causes of death and disability worldwide. The estimated global incidence of acute TBI during 2016 was 27 million cases, and the estimated global prevalence of chronic impairment secondary to TBI was 55.5 million cases.[1] Overall, TBI and long-term motor deficits secondary to TBI significantly impair a person's self-care, employability, and quality of life, and are major burdens on healthcare systems worldwide. In the United States, approximately 43% of surviving hospitalized persons with TBI experience long-term disabilities,[2] and it is estimated that 3.17 million people are living with long-term disabilities secondary to TBI.[3]

About SanBio

SanBio is engaged in the regenerative cell medicine business, spanning research, development, manufacture, and sales of regenerative cell medicines. SanBio targets patients with high unmet medical needs that cannot be addressed by existing medical treatments, mainly in diseases of the central nervous system. SanBio is headquartered in Tokyo, Japan and has subsidiaries based in Mountain View, California, and Singapore. Additional information about SanBio Group is available at https://www.sanbio.com/en/.

Sources:

[1]James SL, et al. "Global, regional, and national burden of traumatic brain injury and spinal cord injury, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016." Lancet Neurol 2019;18:56-87.

[2]Selassie AW, et al. "Incidence of long-term disability following traumatic brain injury hospitalization, U.S.", 2003. J Head Trauma Rehabil 2008;23:123-31

[3]Zaloshnja E, Miller T, Langlois JA, Selassie AW. "Prevalence of long-term disability from traumatic brain injury in the civilian population of the United States, 2005." J Head Trauma Rehabil. 2008 Nov-Dec;23(6):394-400.

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