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Regenerative cell medicine SB623 awarded orphan designation

SanBio Co., Ltd. hereby announces that its regenerative cell medicine SB623, which has been granted Sakigake Designation as a regenerative medicine product, has been awarded orphan designation for its efficacy in improving chronic effects associated with traumatic brain injury (TBI).

Based on Article 77, Paragraph 2 of the Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act, a regenerative medicine product is granted orphan designation if it is intended to treat a disease that affects fewer than 50,000 patients in Japan and satisfies the following criteria:

(1) There is no appropriate alternative drug, medical device, regenerative medicine product, or treatment;
(2) Substantially higher levels of efficacy and safety is expected compared with existing drugs, medical devices, or regenerative medicine products; and
(3) There is a theoretical rationale for using the regenerative medicine product in treating the target disease, and the development plan for the product is appropriate.

If a regenerative medicine product is granted orphan designation, the developer in general can enjoy such benefits as the following: subsidies or tax credits for part of the development expenses incurred between the day the product receives orphan designation to the filing of manufacturing and marketing approval; guidance and consultation as well as priority review from the Ministry of Health, Labour and Welfare (MHLW), the Pharmaceuticals and Medical Devices Agency, and the National Institute of Biomedical Innovation, Health and Nutrition; and an extension of up to 10 years in the re-examination period.

According to a survey conducted by MHLW, the number of patients suffering from chronic effects of TBI in Japan is estimated at 2,100. The survey estimated the total number of patients based on the actual number of patients who had received treatment at medical institutions on the day of the survey. However, the survey also notes that there are patients in the chronic stage of TBI who stay home rather than seeking care at medical institutions because there is no effective treatment. The SanBio Group, while collaborating with relevant patient associations, intends to make contributions to the patients suffering from chronic effects of TBI through offering them a new treatment option. Because drugs that are awarded orphan regenerative medicine designation address high unmet medical needs and target diseases for which there is no alternative treatment, we intend to proceed with the development of SB623 toward approval filing as soon as possible.

The Company Group is making preparations to apply for manufacturing and marketing approval of regenerative cell medicine SB623 for the treatment of chronic effects associated with TBI in Japan within the fiscal year ending January

2021 (February 2020–January 2021).

Reference: Ministry of Health, Labour and Welfare: Overview of Orphan Drug/ Medical Device Designation System
https://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/orphan_drug.html