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SanBio Granted Regenerative Medicine Advanced Therapy Designation from the U.S. FDA for SB623 for the Treatment of Chronic Neurological Motor Deficits Secondary to Traumatic Brain Injury

SanBio Company Limited hereby announces that SanBio Granted Regenerative Medicine Advanced Therapy Designation from the U.S. FDA for SB623 for the Treatment of Chronic Neurological Motor Deficits Secondary to Traumatic Brain Injury as attached.

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Mountain View, Calif.—September 19, 2019— The SanBio Group (SanBio Co., Ltd. and SanBio, Inc.), a scientific leader in regenerative medicine for neurological disorders, today announced that the U.S. Food and Drug Administration (FDA) has granted Regenerative Medicine Advanced Therapy (RMAT) Designation for SB623 cell therapy for the treatment of chronic neurological motor deficits secondary to traumatic brain injury (TBI). The designation is based on clinical results of SB623 including the Phase 2 Study of Modified Stem Cells in Traumatic Brain Injury (STEMTRA) trial.

Created under the 21st Century Cures Act, the RMAT designation is reserved for a regenerative medicine therapy intended to treat, modify, reverse, or cure a serious condition, and clinical evidence indicates that the therapy has the potential to address unmet medical needs for such disease or condition. Similar to the Breakthrough Therapy designation, the RMAT designation offers sponsors of cell and gene therapies eligibility for expedited development and regulatory review of their product candidate, including earlier and more frequent consultation with the FDA, and the potential for Priority Review and Accelerated Approval.

“The RMAT designation for SB623 is an important regulatory milestone for SanBio as we investigate it as a treatment option for patients with chronic neurological motor deficits resulting from a traumatic brain injury,” said Bijan Nejadnik, M.D., Chief Medical Officer and Head of Research. “TBIs are one of the most common health conditions worldwide that often cause long-term complications or death. We look forward to working with the FDA on a potentially accelerated clinical development program to address this serious unmet medical need.”

The RMAT designation augments the Sakigake Designation for innovative medical products from the Ministry of Health, Labour, and Welfare of Japan.

About SB623
SB623 is a proprietary, cell-based investigational product made from modified and cultured adult bone marrow-derived mesenchymal stem cells that undergo temporary genetic modification. Implantation of SB623 cells into injured nerve tissue in the brain is expected to trigger the brain’s natural regenerative ability to recover lost motor functions.

SanBio expects to initiate a Phase 3 trial for SB623 for the treatment of chronic neurological motor deficits secondary to TBI by the end of the fiscal year ending January 31, 2021. SB623 is also currently in a Phase 2b clinical trial for treatment of chronic motor deficit resulting from ischemic stroke.

About the Study of Modified Stem Cells in Traumatic Brain Injury (STEMTRA) Trial
STEMTRA was a 12-month, Phase 2, randomized, double-blind, surgical sham-controlled, global trial evaluating the efficacy and safety of SB623 compared to sham surgery in patients with stable chronic neurological motor deficits secondary to TBI. In this study, SB623 cells were implanted directly around the site of brain injury.

To be eligible for this trial, patients (ages 18-75) must have been at least 12 months post-TBI and had a Glasgow Outcome Scale extended (GOS-E) score of 3-6 (e.g., moderate or severe disability). Patients must also have been able to undergo all planned neurological assessments and had no seizures in the prior three months. The primary endpoint was mean change from baseline in Fugl-

Meyer Motor Scale (FMMS) score which measures changes in motor impairment at six months. The STEMTRA trial enrolled 61 patients from 13 surgical and 18 assessment sites in the U.S., Japan and Ukraine.

In this study, SB623 met its primary endpoint, with patients treated with SB623 achieving an average 8.3 point improvement from baseline in the FMMS, versus 2.3 in the control group, at 24 weeks (p=0.040). Of patients treated with SB623, 18 (39.1%) reached a 10 or more point improvement of FMMS compared to one control patient (6.7%; p=0.039). No new safety signals were identified. The most commonly reported adverse event were headaches.

About SanBio Group (SanBio Co., Ltd. and SanBio, Inc.)
SanBio Group is a regenerative medicine company with cell-based products focused on neurological disorders in various stages of research, development and clinical trials. The Company's lead asset, SB623, is currently being investigated for the treatment of several conditions including chronic neurological motor deficit resulting from ischemic stroke and traumatic brain injury. SanBio has received a Japanese marketing license for regenerative medicine products from the Tokyo Metropolitan Government, and plans to begin marketing regenerative medicine products in Japan by the end of the fiscal year ending January 31, 2021. The Company is headquartered in Tokyo, Japan and Mountain View, California, and additional information about SanBio Group is available at https://sanbio.com.

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