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Notice regarding completion of comprehensive Sakigake evaluation consultation and commencement of preparations for approval filing for Japan SB623 chronic TBI program

SanBio Co., Ltd. (Tokyo, Chuo-ku; Representative Director and President: Keita Mori) (the "**Company**") annouces as follows that the Company group (SanBio Co., Ltd. and its subsidiaries SanBio Inc. and SanBio Asia Pte. Ltd.; the "**Company Group**") has received five application confirmation documents dated January 31, 2022 from the Pharmaceutical and Medical Devices Agency ("**PMDA**") in conjunction with the conclusion of the comprehensive Sakigake evaluation consultation for the Japan SB623 chronic TBI program and that pursuant to its receipt of such documents it has now commenced preparations toward filing for approval.

The Japan SB623 chronic TBI program received "Sakigake review" designation under the "Sakigake review designation system" as a regenerative medicine product, and the Company Group is proceeding with preparations toward filing for approval within the framework of the Sakigake review designation system. The Sakigake review designation system is a system aimed at limiting the period between filing for approval and receiving approval to six months by reducing the time required for post-filing regulatory review. The process for products that receive Sakigake designation is as follows. First, the PMDA provides in-person advice and conducts preliminary interviews with the filing party. Then, comprehensive Sakigake evaluation consultations are held and the filing party receives five application confirmation documents related to "clinical, "non-clinical," "quality," "reliability," and "GCTP." After this, an approval application can be filed.

The Company Group has received all five application confirmation documents from the PMDA as of January 31, 2022, and has therefore begun preparations toward filing for approval. The Company expects to file for approval within approximately one month.

The timing of filing for approval is based on a reasonable estimate made by the Company at the moment, but there may be delays depending on the preparation status and other factors.

It is currently being assessed whether there is any impact on the financial outlook. The Company will promptly make an announcement if there is determined to be any impact on the Company Group's consolidated earnings performance outlook for the fiscal year ending January 2023.