December 15, 2020
SanBio Co., Ltd.

Notice regarding the status of domestic approval filing for regenerative cell medicine SB623 for treatment of chronic effects associated with traumatic brain injury

Regarding the regenerative cell medicine SB623 for treatment of chronic effects associated with traumatic brain injury (TBI program) under development by the Company Group (SanBio Co., Ltd. and its subsidiary SanBio Inc.), the Company has been actively engaged in consultations with the Pharmaceutical and Medical Devices Agency (PMDA) under the Sakigake Designation System with the aim of applying for manufacture and marketing approval in Japan during the current fiscal year (February 2020–January 2021). However, the Company expects that filing for approval of the investigational product is likely to be delayed.

The Company Group will continue to do its utmost to obtain authorization to file for approval of SB623 from PMDA, and to be able to make an announcement regarding approval filing as soon as possible. However, details regarding matters discussed in consultations with PMDA, including the time it may take to obtain PMDA authorization to file for approval and to be actually granted approval for the investigational product, should be handled with caution as these also contain highly confidential information about the Company Group's technology. As a result, the Company has decided to refrain from disclosing details and status of its consultations with PMDA, including expected timing of approval filing. We will promptly make a disclosure as soon as we file for approval and obtain approval for the investigational product.

For supplementary explanation regarding this matter, please see Supplementary Q&A uploaded on the Company website (https://www.sanbio.com/en/ir/).

This matter will have no impact on the Company Group's consolidated earnings performance for the fiscal year ending January 2021.

About SB623

SB623 is an allogeneic mesenchymal stem cell produced by modifying and culturing bone marrow derived from healthy donors. Implantation of SB623 cells into nerve tissues is expected to promote regeneration of damaged nerve cells. Because SB623 is made from allogeneic cells, large-scale production is possible and there is no need for complex cell processing required for treatments using autologous cells, e.g., cell preparation for each patient at medical institutions. Hence, pharmaceutical products made from allogeneic cells, such as SB623, can be provided to many patients in uniform quality.

About SanBio Co., Ltd. and SanBio, Inc.

SanBio Group is engaged in the regenerative cell medicine business, spanning research, development, manufacture, and sales of regenerative cell medicines. The Company's propriety regenerative cell medicine product, SB623, is currently being investigated for the treatment of several conditions including chronic neurological motor deficit resulting from traumatic brain injury and ischemic stroke. 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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