

July 29, 2024

Company SanBio Co., Ltd.

name: (Code: 4592 TSE Growth)

Name of Keita Mori, Representative Director and

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# Notice Concerning Notice of Allowance of New Patent for Cell Therapy Using SB623 for Chronic Ischemic Stroke in the US

SanBio Co., Ltd. hereby provides on this matter as per the attached document.



## Notice Concerning Notice of Allowance of New Patent for Cell Therapy Using SB623 for Chronic Ischemic Stroke in the US

SanBio Co., Ltd. (Head office: Tokyo, Representative Director and President: Keita Mori) and its subsidiary SanBio, Inc. hereby announce that the US Patent and Trademark Office has issued Notice of Allowance of the patent application SanBio, Inc. filed for its key development product SB623 (INN: vandefitemcel) for the treatment of chronic ischemic stroke on July 15, 2024.

Details of the patent which we have received Notice of Allowance is as below.

Name of invention: CELL THERAPIES AND METHODS OF TREATMENT FOR

SMALL-VOLUME STROKE

Country of filing: US

Patent application number: US 17/664,856 Notice of allowance date: July 15, 2024

Applicant: SanBio, Inc. Mountain View, CA (US)

The Notice of Allowance was issued for the patent application submitted based on the results of the Phase 2b clinical trial of SB623 in chronic ischemic stroke patients in the US (STR-02 study). Additional analysis of the study indicated that among patients with an infarction volume of 50cc or less (77 out of 163 patients), the percentage of patients that demonstrated composite improvement in the Fugl-Meyer Motor Scale score was significantly higher in the treatment group than in the sham surgery (control) group<sup>1</sup>. Based on the results of the additional analysis, the Notice of Allowance was issued for the cell therapy using SB623 to treat chronic ischemic stroke patients with an infarction volume less than 50cc.

As part of its efforts to maximize corporate value, SanBio is focused on building and maintaining its patent portfolio. The Notice of Allowance of the patent significantly will extend the term of the use patent for SB623 for the treatment of chronic ischemic stroke in the US, the largest market.

With the Notice of Allowance, SanBio will continue exploring ways to expand the indications of SB623 to include chronic ischemic stroke. This matter will have only a minimal impact on the financial performance of the current fiscal year.

### About SanBio Group (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 mainly focuses on diseases of the central nervous system that cannot be addressed by existing medical and pharmaceutical products and for which there is a high unmet medical need. The Company is headquartered in Tokyo, Japan and Oakland, California, and additional information about SanBio Group is available at <a href="https://sanbio.com/en/">https://sanbio.com/en/</a>

#### **About Stroke**

Stroke is a condition caused by a blood clot blocking a blood vessel in the brain, leading to insufficient blood supply to brain cells. It is estimated that there are 6.85 million stroke patients in the US<sup>2</sup> and 1.19 million in Japan<sup>3</sup>. Early treatment and intervention are crucial, as severe disabilities may become permanent once the condition enters the chronic phase. Current treatments for stroke patients in the chronic phase include pharmacotherapy to prevent recurrence and rehabilitation. However, there are no drugs available that fundamentally address and treat chronic motor function disorders caused by stroke, indicating a high unmet medical need.

#### <References>

- <sup>1</sup> For details, please see pg. 27 of the "Business Plan and Matters Concerning Growth Potential," released on April 25, 2024
- <sup>2</sup> Company analysis based on multiple sources
- <sup>3</sup> The number of "Cerebral infarction" patients in *Patient Survey 2020*, the Ministry of Health, Labour and Welfare

#### For more information, contact:

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