三生制药
3SBIO INC.

(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 1530)

VOLUNTARY ANNOUNCEMENT

Narfuraphine hydrochloride orally disintegrating tablets co-developed by 3SBio Inc. and Toray in Japan approved for launch in the market

3SBio Inc. (the "**Company**") wishes to provide to the shareholders of the Company the attached press release in respect of the new drug application of narfuraphine hydrochloride (R&D Code: TRK-820) orally disintegrating tablets (麗美治®, trade name in Japan: "レミッチOD錠2.5μg") submitted to the National Medical Products Administration of China (NMPA) being approved for launch in the market.

This is a voluntary announcement made by the Company. There is no assurance that the Company will eventually successfully launch and/or commercialize the product. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
3SBio Inc.
Dr. LOU Jing
Chairman

Shenyang, the PRC
5 July 2023

As at the date of this announcement, the Board comprises Dr. LOU Jing and Ms. SU Dongmei as executive Directors; Mr. HUANG Bin as non-executive Director; and Mr. PU Tianruo, Ms. YANG, Hoi Ti Heidi, Mr. NG, Joo Yeow Gerry, and Dr. ZHANG Dan as independent non-executive Directors.

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Press Release

Narfuraphine hydrochloride orally disintegrating tablets co-developed by 3SBio Inc. and Toray in Japan approved for launch in the market

3SBio Inc. announced today that the new drug application of narfuraphine hydrochloride orally disintegrating tablets (麗美治®, trade name in Japan: "レミッチOD錠2.5μg") submitted to the National Medical Products Administration of China (NMPA) has been approved (Guoyaozhunzi No. HJ20230091) for the improvement of pruritus in hemodialysis patients (only in cases where the efficacy of existing treatments is not satisfactory). This is the first and only selective κ (kappa)-opioid receptor agonist approved by the NMPA to treat hemodialysis patients with refractory pruritus. In addition, the clinical trial application for this product to improve pruritus in patients with chronic liver disease (only in cases where the efficacy of existing treatments is not satisfactory) was approved in May this year (Notice No.: 2023LP00912).

Hemodialysis patients are often accompanied by various complications such as anemia, hypertension, abnormal calcium and phosphorus metabolism, hyperthyroidism, and pruritus. Currently, there is still no recognized effective treatment for pruritus in most of the patients, which causes great mental and physical pain to the patients and significantly reduces their quality of life. It is generally believed that pruritus in hemodialysis patients is caused by multiple factors and is related to disorders of the endogenous opioid system and abnormal itch control mechanisms in the brain. These factors are believed to be the main reasons for the greater resistance against existing treatments such as antihistamines, steroids, and moisturizers.

Narfuraphine hydrochloride is a selective κ (kappa)-opioid receptor agonist independently developed by Toray Industries, Inc., which exerts antipruritic effect through a new mechanism of action completely different from that of existing antihistamines or antiallergic drugs. Clinical trials conducted in Japan have confirmed that the drug still has significant curative effect on hemodialysis pruritus that is resistant to existing treatments. In 2009, soft capsule dosage-form of narfuraphine hydrochloride was approved in Japan for the improvement of pruritus in hemodialysis patients (only in cases where the efficacy of existing treatments is not satisfactory), and subsequently, indications including pruritus in chronic liver disease patients and pruritus in peritoneal dialysis patients (only in cases where the efficacy of existing treatments is not satisfactory) were also approved in Japan. Orally disintegrating tablets were also approved for launch in the market in Japan in 2017, which improved drug-intake convenience and compliance for patients with impaired swallowing function or patients with restricted water intake. In December 2017, Toray Industries, Inc. granted 3SBio Inc. the exclusive right to develop and commercialize the formula of narfuraphine hydrochloride orally disintegrating tablets in the People's Republic of China, excluding Hong Kong, Macau and Taiwan.

The Phase III bridging study enrolled 141 hemodialysis patients with refractory pruritus. The effectiveness results indicated that narfuraphine hydrochloride orally disintegrating tablets can effectively treat hemodialysis patients with refractory pruritus. The VAS changes in both the 5μg group and the 2.5μg group were significantly greater than those in the placebo groups, among which the difference of the least square mean value of VAS change between the 5μg group and the placebo group was 11.37mm, and that difference between the 2.5μg group and the placebo group was 8.81mm. These differences were all greater than the effect size in the null hypothesis, confirming the success of the 5μg and 2.5μg doses in the bridging study, and were consistent with the conclusion of the validation trial in Japan. The safety results indicated that narfuraphine hydrochloride orally disintegrating tablets had a good safety profile in Chinese patients. There were no occurrences of serious adverse reactions nor adverse reactions leading to withdrawal from the trial or death. The Phase I study estimated the PK characteristics of narfuraphine hydrochloride orally disintegrating tablets in the Chinese population. The racial sensitivity assessment report indicated that narfuraphine hydrochloride has a low risk of racial differences between Chinese and Japanese populations. The results of PopPK analysis also verified that the pharmacokinetic characteristics of narfuraphine hydrochloride in the Chinese population were similar to those in the Japanese population.

Dr. LOU Jing, chairman of 3SBio Inc., said, "We are very excited that narfuraphine hydrochloride orally disintegrating tablets have successfully entered the Chinese market. We also look forward to this product bringing a new treatment option for pruritus in hemodialysis patients (only in cases where the efficacy of existing treatments is not satisfactory). 3SBio Inc. will continue to leverage its own advantages, accelerate the pace of independent research and development and cooperation, and bring more high-quality medicines to patients in China."

About 3SBio Inc.

3SBio Inc. is a leading bio-pharmaceutical company integrating research and development ("**R&D**"), production and sales, with a focus on improving the life quality of patients with high-quality medicines to benefit human health. At present, the Company owns more than 100 national invention patents and has launched more than 30 kinds of products into the market, covering several treatment fields, including, among others, nephrology, oncology, autoimmune, ophthalmology and dermatology. The Company owns four R&D centers of the National Engineering Research Center of Antibody Medicine and dual platforms for biopharmaceutical and chemical medicine. There are 31 kinds of products under R&D, 26 kinds of them are national new drugs. The Group also owns five production bases complying with the GMP standards. In the future, 3SBio Inc. will continue to uphold the concept of "Care for Life, Cherish Life, Create Life" to create a world-leading biopharmaceutical company in China. Please visit www.3sbio.com for additional information.

About Toray

Established in 1926, Toray Industries Inc. is a world-renowned comprehensive chemical company. Toray seeks to change the world by continuing innovation through the power of chemistry. Currently, Toray has 290 affiliated companies in 29 countries and regions all over the world, carrying out related businesses in various fields such as fibers, functional chemical products, carbon fiber composite materials, life sciences, environment and engineering worldwide. Please visit www.toray.cn for more information about Toray.

Cautionary Notes and Forward-Looking Statements

This press release contains forward-looking statements, such as those relating to business and product outlook, or the Company's intent, plans, beliefs, expectation and strategies. These forward-looking statements are based on information currently available to the Company and are stated herein on the basis of the outlook at the time of this press release. These forward-looking statements are based on certain expectations, assumptions and premises, some of which are subjective or beyond our control. These forward-looking statements may prove to be incorrect or may not be realized in the future. With respect to any new product or new indication for a product, we cannot guarantee that it will be successfully developed or ultimately marketed. Such forward-looking statements are subject to various risks and uncertainties. Further information regarding such risks and uncertainties may be found in our other public disclosure documents. The scientific information involved may only be preliminary and empirical. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.