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三生制药
3SBIO INC.

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

VOLUNTARY ANNOUNCEMENT

3SBio's long-acting erythropoietin SSS06 project has completed the enrolment of the first subject for phase III clinical study

3SBio Inc. (the “**Company**”) wishes to provide to the shareholders of the Company the attached press release in respect of the recombinant erythropoietin stimulating protein (rESP, CHO cell) injection (drug code: SSS06) developed by the Company, which is currently undergoing a “multicentered, randomized, parallel-controlled phase III clinical study for the comparison of using intravenous injection of recombinant erythropoietin stimulating protein injection (CHO cell) and EPIAO to maintain the efficiency and safety of treatment among the patients receiving hemodialysis who suffer from chronic kidney disease and anemia”. Recently, the first subject has been enrolled into the clinical study, and the first administration of the drug has been successfully completed in accordance with the treatment plan.

This is a voluntary announcement made by the Company. The Company cannot guarantee that it is able to successfully develop or eventually launch and/or commercialize such 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
15 March 2022

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

3SBio's long-acting erythropoietin SSS06 project has completed the enrolment of the first subject for phase III clinical study

15 March, 2022

3SBio Inc. (01530.HK) (“**3SBio**” or “**Company**”) announced today that the recombinant erythropoietin stimulating protein (rESP, CHO cell) injection (drug code: SSS06) developed by 3SBio is undergoing a “multicentered, randomized, parallel-controlled phase III clinical study for the comparison of using intravenous injection of recombinant erythropoietin stimulating protein injection (CHO cell) and EPIAO to maintain the efficiency and safety of the treatment among the patients receiving hemodialysis who suffer from chronic kidney disease and anemia”, and such clinical study has recently completed the enrolment of its first subject and successfully completed the first administration of the drug in accordance with the treatment plan.

Clinical data from phase I and II study completed at earlier stage demonstrates that SSS06 has good safety and tolerability, a longer half-life period and stability, and no production of anti-drug antibody (ADA) was detected, which can significantly reduce the dosing frequency and provide more convenient treatment for patients. In light of the good safety and efficiency demonstrated by the main data of phase II study, CDE approved the initiation of phase III clinical study for SSS06.

Clinical data in recent years has shown that rHuEPO has a short half-life period and requires frequent dosing, causing inconvenience to patients and medical personnel. Therefore, there is an urgent clinical need to develop safe, stable and efficient rHuEPO with a longer in-vivo elimination half-life. SSS06 utilizes the recombinant DNA technology to conduct site-directed mutagenesis on rhEPO gene. The long-acting recombinant high glycosylation protein product is produced by adding three N-linked glycosylation sites. The restructured rESP preserves the original biological activity while having longer stability and half-life period, which can reduce the dosing frequency and provide convenience for clinical use.

Anemia is a common complication of Chronic Kidney Disease (CKD), the incidence of which gradually increases along with the decrease in kidney function. When a patient with chronic kidney disease enters into phase 5, i.e. end-stage renal disease (ESRD), the incidence of anemia could be as high as 98%⁽¹⁾. As endogenous EPO is mainly produced in kidney, during the development of chronic kidney disease, the gradual damage to the kidney tissue causes insufficient secretion of endogenous EPO, resulting in renal anemia.

Anemia often occurs in the early stages of the development of chronic renal failure. The degree of renal anemia of chronic renal failure patients receiving hemodialysis would directly affect the body function, physical pain, general health, mental health and other life quality indicators of patients, which ultimately affects the survival rate of patients. For patients with chronic renal failure who requires hemodialysis, correction of hemoglobin level in a timely manner may significantly improve their quality of life and body functions.

“We are glad to see that phase III clinical trial of SSS06 has successfully launched. The erythropoietin of the Company has been highly recognized by a vast number of doctors and patients since its launch. However, we are still striving to improve the half-life period and efficiency of the product, in order to reduce the dosing frequency and provide patients with a more convenient and better medication experiences. Through the iterative update of our products, we repay the trust and expectations the patients and doctors have in us.” said Dr. LOU Jing, Chairman of 3SBio.

Reference: (1) Lin Pan, Ding Xiaoqiang, etc. Fudan University Journal of Medical Sciences, 2009 Sep, 36(5)