



September 20, 2019  
Gene Techno Science Co., Ltd.  
Code: 4584 (TSE Mothers)  
Masaharu Tani, President & CEO

## **Announcement of Receiving Manufacturing and Marketing Approval for Darbepoetin Alpha Biosimilars in Japan**

Tokyo, September 18, 2019 – Gene Techno Science Co., Ltd. (TSE Mothers: 4584 “GTS”). Sanwa Kagaku Kenkyusho Co., Ltd. (“SKK”) has received manufacturing and marketing approval for darbepoetin alpha biosimilars (genetical recombination) from the Ministry of Health, Labor and Welfare effect on September 20, which has been jointly developed by both companies.

GTS entered into an agreement with SKK for the joint development of darbepoetin alpha biosimilars on January 21, 2014 and have been proceeding with the development of biosimilar for darbepoetin alpha (genetical recombination), a long-acting erythropoiesis stimulating protein. Subsequently, based on the results of a phase III clinical study in Japan for the non-dialysis and dialysis patients of chronic kidney disease with nephrogenic anemia, SKK submitted a new drug application in September 2018 and received approval as the drug for nephrogenic anemia. SKK concluded a licensing agreement with Dong-A ST Co., Ltd. of South Korea for the development and commercialization of this drug in Japan. DM Bio Limited, which specializes in biopharmaceuticals, established by Dong-A Socio Holdings Co., Ltd (holding company of Dong-A ST) and Meiji Seika Pharma Co., Ltd, manufacture this product from drug substance to formulation. Manufacturing and marketing are conducted independently by SKK, and GTS earns royalty income according to sales.

In addition to providing new options in the field of kidney disease, we believe this drug is economically viable as a biosimilar, which contributes both “sustainability of universal health insurance system” and “promotion of innovation” and also benefits the public from the viewpoint of realizing "reducing the public financial burden" and "improving medical quality".

GTS announced GTS 3.0 “Biotech Engineering Company, striving for value creation” a new business stage starting from this fiscal year, which targeted the pediatric disease in addition to the areas GTS has been engaged in such as the orphan disease and intractable disease. By leveraging the knowhow and expertise about biotechnology acquired in the past business activities, GTS is working on the development and provision of new medicines and therapeutic treatment for the purpose of achieving comprehensive healthcare solutions for the patients suffering from these diseases as well as families and caregivers. This is the second product to be launched in the biosimilar business following Filgrastim BS, and not only the revenues generated by these biosimilars but also the accumulated expertise and know-how through the process of launching these products will promote our GTS3.0 by accelerating research and development of new biologics and regenerative medicine products in the new biotech business.

The impact of this transaction on the business results for the fiscal year ending March 2020 is expected to be minimal.