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Takara Bio Announces Transfer of SAKIGAKE and Orphan Designations for NY-ESO-1/siTCR™ Gene Therapy Product

Shiga Japan - January 24, 2023 - Takara Bio Inc., an innovative biotechnology company, announces the transfer of the designated applicant under SAKIGAKE Designation System (hereinafter, “SAKIGAKE”) and the Orphan Regenerative Medicine designation, in regards to NY-ESO-1/siTCR™ gene therapy product (Development code: TBI-1301, International nonproprietary name: mipetresgene autoleucl) for synovial sarcoma.

NY-ESO-1/siTCR™ gene therapy product has received its initial SAKIGAKE designation from the Ministry of Health, Labour and Welfare in March 2018. The designation was transferred to Otsuka Pharmaceutical Co., Ltd. (Otsuka) in February 2019 based on the co-development and exclusive marketing agreement with them. The Orphan Regenerative Medicine designation was also granted in June 2020 for the treatment of synovial sarcoma. Following the termination of agreement with Otsuka on November 10, 2022, these designations were transferred to Takara Bio as of January 20, 2023.

Takara Bio has been proceeding with the preparation for the application for marketing authorization based on the Phase I/II clinical trial of NY-ESO-1/siTCR™ in Japan for synovial sarcoma.

Forward-Looking Statements

Statements contained in these materials with respect to the Company’s current plans, forecasts, strategies and beliefs that are not historical facts are forward-looking statements about the further performance of the Company and its consolidated subsidiaries. These statements are based on management’s assumptions and beliefs in light of information currently available to it, but are based on a number of assumptions and beliefs derived from information that contains significant risks and uncertainties. Actual results may differ materially from these forecasts due to various factors. Factors that could influence actual results include, but are not limited to, economic conditions, especially trends in consumer spending, as well as exchange rate fluctuations, changes in laws and government systems, pressure from competitors’ prices and product strategies, declines in selling power of the Company’s existing and new products, disruptions to production, violations of our intellectual property rights, rapid advances in technology, and unfavorable verdicts in major litigation.