Sumitomo Dainippon Pharma

News Release

July 2, 2019

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Announces Discontinuation of Phase 3 CanStem111P Study of Investigational Anti-Cancer Agent Napabucasin in Patients with Pancreatic Cancer Following Interim Analysis

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) announced today that its U.S. subsidiary, Boston Biomedical, Inc. has received a recommendation on July 1, 2019 (U.S. Time) from the independent Data and Safety Monitoring Board (DSMB) to discontinue the Phase 3 CanStem111P study of evaluating the safety and efficacy of investigational agent napabucasin (generic name, product code: BBI608) for patients with pancreatic cancer due to the futility. Sumitomo Dainippon Pharma has accepted the recommendation and decided to discontinue the study for patients with pancreatic cancer.

The DSMB recommendation has been prepared based on the interim analysis results at the point in the study where 50% of total events for the study have occurred. No new safety concerns were raised by the DSMB.

Sumitomo Dainippon Pharma is currently evaluating the impact that this matter will have on its consolidated financial results of the fiscal year ending March 31, 2020, and will promptly make a disclosure if there arises a need for revision of earnings forecast of such fiscal year or there occurs any other reportable event in relation to this matter.

Napabucasin is currently being investigated in a Phase 3 study for colorectal cancer.

About Napabucasin

Napabucasin is an orally-administered investigational anti-cancer agent created by Boston Biomedical, Inc., wholly-owned subsidiary of Sumitomo Dainippon Pharma. Napabucasin is bioactivated by the enzyme NQO1 in cancer cells, which generates reactive oxygen species (ROS) to inhibit cancer stemness and tumor progression-related pathways including the STAT3, expected to ultimately result in cancer cell death.

Contact:
Corporate Communications
Sumitomo Dainippon Pharma Co., Ltd.
TEL: +81-6-6203-1407 (Osaka); +81-3-5159-3300 (Tokyo)