Sumitomo Dainippon Pharma

News Release

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Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Announces Topline Results of Phase 3 Study on Investigational Anti-Cancer Agent Napabucasin Fails to Reach Primary Endpoints in Patients with Colorectal Cancer

Sumitomo Dainippon Pharma Co., Ltd. (Head Office, Osaka, Japan; Representative Director, President and CEO, Hiroshi Nomura) announced today the topline results that the Phase 3 CanStem303C study evaluating the safety and efficacy of investigational anticancer agent napabucasin (generic name; development code, BBI608; hereafter, "napabucasin") failed to reach the primary endpoints.

The safety profile was consistent with that in the previous clinical studies of napabucasin.
The detailed results of the study will be presented at scientific meetings in the future.

We are currently reviewing our consolidated financial forecasts for the fiscal year ending March 2021 based on the results of this study and our recent performance trends and will promptly make further announcements if we revised the financial forecasts.

About the CanStem303C study (NCT02753127)

The CanStem303C study is a global, multicenter, open-label, randomized phase 3 study to evaluate the efficacy and safety of napabucasin in 1,253 patients with previously treated metastatic colorectal cancer. Patients were randomized 1:1. Napabucasin at a dose of 240 mg was administered orally, twice daily in combination with FOLFIRI (combination of fluorouracil, leucovorin, irinotecan) versus FOLFIRI. FOLFIRI was administered with bevacizumab at the discretion of the investigator.
The primary endpoints are overall survival (OS) in the general study population and the pSTAT3 positive subpopulation. Key secondary endpoints are progression free survival (PFS), disease control rate (DCR) and overall response rate (ORR) in the general study population and pSTAT3 positive subpopulation.

About Napabucasin

Napabucasin is an orally administered small molecule investigational anti-cancer agent created by Sumitomo Dainippon Pharma Oncology, Inc. (formerly Boston Biomedical, Inc.), a 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 STAT3, which is expected to result in cancer cell death.

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