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Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Announces Recommendation to Continue Phase 3 CanStem303C Study of Investigational Anti-Cancer Agent Napabucasin in Patients with Colorectal Cancer Following Interim Analysis

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) today announced that its U.S. subsidiary, Boston Biomedical, Inc. has received a recommendation from the independent Data and Safety Monitoring Board (DSMB) to continue the Phase 3 CanStem303C study of evaluating the safety and efficacy of investigational agent napabucasin (generic name, product code: BBI608) for patients with colorectal cancer. According to the recommendation, Sumitomo Dainippon Pharma will continue the study as planned.

The DSMB recommendation is based on the interim analysis results at the point where 50% of the total events of the study occurred which met the pre-specified threshold.

About Napabucasin

Napabucasin is an orally administered small molecule investigational anti-cancer agent created by 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.

Napabucasin is currently being investigated in a phase 3 trial for colorectal cancer and a phase 3 trial for pancreatic cancer. It is also being investigated in earlier phase trials in multiple solid cancers. In 2016, the U.S. Food and Drug Administration granted Orphan Drug Designation for napabucasin in pancreatic cancer.

About the CanStem303C study (NCT02753127)

The CanStem303C study is a randomized, open label global clinical phase 3 study to evaluate the efficacy and safety of administration of napabucasin plus FOLFIRI in comparison with FOLFIRI with or without bevacizumab per investigator choice in the U.S., Japan and etc. A total of 1,253 patients with previously treated metastatic colorectal cancer, was randomized in a 1:1 ratio to napabucasin group or control group. The primary endpoint is overall survival (OS) in the general population and in the pSTAT3(+) subpopulation.

The interim analysis of the CanStem303C study was performed when the cumulative number of events reached 425.

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