Sumitomo Dainippon Pharma

News Release

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Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Announces Unblinding of Phase 3 Study of Napabucasin, a cancer stemness inhibitor, in Patients with Gastric/GEJ Cancer

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; President: Masayo Tada) announced today that the Company decided to unblind the BRIGHTER study, a phase 3 global study in patients with gastric and gastro-esophageal junction (GEJ) cancer of napabucasin (generic name, product code: BBI608), an investigational cancer stemness inhibitor, based on a recommendation by the study's independent Data and Safety Monitoring Board (DSMB), following a pre- specified interim analysis.
The study will be continued as an open label study to follow all endpoints as defined in the protocol.

The DSMB determined that the study was unlikely to reach its primary endpoint of superior overall survival for the napabucasin arm versus the control arm at the conclusion of the study. No safety concerns were identified by the DSMB.

Sumitomo Dainippon Pharma remains committed to other ongoing phase 3 studies (CanStem303C for colorectal cancer, CanStem111P for pancreatic cancer) with an aim to obtain marketing authorization of napabucasin as early as possible.

"Advanced gastric/GEJ cancer is a tumor type with high unmet need, and our hope was to develop a new therapeutic option for these patients. We are disappointed with the results of this interim analysis," said Patricia S. Andrews, Chief Executive Officer, Boston Biomedical, Inc. "We remain committed to our ongoing studies with napabucasin as well as our other first-in-class investigational compounds."

Sumitomo Dainippon Pharma is currently examining the effects that this matter will have on its consolidated business performance and will promptly make an announcement if it finds that there is a need to make further disclosures.

<Reference information>

【About napabucasin】
Napabucasin is an investigational first-in-class anti-cancer agent created by Boston Biomedical, Inc., wholly-owned subsidiary of Sumitomo Dainippon Pharma. Napabucasin is an orally administered small molecule agent with a novel mechanism of action designed to inhibit cancer stemness pathways by targeting STAT3. Besides the gastric and GEJ cancer, napabucasin is currently being investigated in phase 3 studies for advanced colorectal and pancreatic cancer.

【About the BRIGHTER study】

The BRIGHTER study is a randomized, double blind global clinical phase 3 study to evaluate the efficacy and safety of administration of napabucasin plus weekly paclitaxel in comparison with weekly paclitaxel alone in the U.S., Japan and etc. A total of 714 patients with advanced gastric and GEJ cancer were previously treated with one prior line of platinum/fluoropyrimidine-containing regimen, randomized in a 1:1 ratio to receive napabucasin plus weekly paclitaxel or weekly paclitaxel alone. The primary endpoint is overall survival (OS) in the general study population; secondary endpoints include progression free survival (PFS), OS and PFS in a predefined biomarker-positive sub-population, objective response rate, disease control rate, and safety.

The interim analysis of the BRIGHTER study was performed when the cumulative number of events reached 380.

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