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**Dainippon Sumitomo Pharma announces BBI608 Phase 1/2 Clinical Study Data
 (Dose-Escalation Study) was presented at the 2013 ASCO Annual Meeting**

Osaka, Japan, June 4, 2013 – Dainippon Sumitomo Pharma Co., Ltd. (DSP) (Headquarters: Osaka, Japan; President: Masayo Tada) announces that the dose-escalation study results from the Phase 1/2 clinical study on BBI608, an anti-cancer treatment under development, was presented on June 3, 2013 (U.S. time) at the 2013 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.

1. Objectives of the study

The Phase 1/2 clinical study was initiated in March 2009 with the aim to determine the safety, tolerability, Recommended Phase 2 Dose (RP2D), pharmacokinetics (PK) and preliminary anti-tumor activity of BBI608. After achieving the objective for this study, the extension study for colorectal cancer patients was conducted with fixing the dose at recommended dose. Phase 3 study (target: 650 subjects) was initiated in January 2013.

(BBI608 Monotherapy Clinical Development Status)

	Stage	Study Outline	Aim of Study	Subjects	Name of Study	Region
This Study	Phase 1/2 Clinical Study	Dose Escalation Study	Determine the Safety, tolerability , Recommended Phase 2 Dose (RP2D), pharmacokinetics (PK) and preliminary anti-tumor activity of BBI608	Adult patients with advanced cancer who had failed standard therapies	101 Study	North America
(Reference)	Phase 1/2 Clinical Study	Extension study	Obtain data for response rate/PFS/OS	Adult patients with advanced colorectal cancer who had failed standard therapies	101 Study	North America

	Phase 3 Clinical Study	Double-blinded comparative study	Verify the efficacy and safety with over 600 patients	Adult patients with advanced colorectal cancer who had failed standard therapies	CO23 Study	North America
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*This study is the dose escalation study in the BBI608-101 study (Phase 1/2 Clinical Study) registered on the ClinicalTrials.gov in the U.S.

2. Outline of the study

This study was conducted in 41 adult patients with advanced cancer including colorectal (CRC), head and neck, gastric, ovarian, melanoma, and breast cancer who had failed standard therapies. Patients were administered BBI608 orally 1-3 times a day for 4 weeks as a cycle. Cycles were repeated until disease progression, unacceptable toxicity, or other discontinuation criteria were met. Fourteen cohorts were dosed from 20 mg to 2000 mg/day.

3. Results of the study

Adverse events for BBI608 were generally mild; the most common being grade 1-2 diarrhea, nausea, anorexia and fatigue with a total of 4 grade 3 events (diarrhea and fatigue), and there were no grade 4 events. MTD was not reached. Hematological toxicity was not observed. The recommended dose for the BBI608 Phase 1/2 clinical study (extension study) was established as 500mg twice daily.

For a preliminary efficacy results (RECIST v1.1), the disease control rate (DCR) was found to be 65% (17/26 evaluable patients). In the subset of 18 patients with colorectal cancer (CRC), among those evaluable, DCR was 67%, median progression free survival (PFS) was 14 weeks and median overall survival (OS) was 47 weeks. Median OS for biomarker-positive (nuclear β -catenin and high p-Stat3) CRC patients was 53 weeks and 54 weeks, respectively.

As its highest priority, DSP focuses on the successful development of BBI608, the world's first anti-cancer treatment to target cancer stem cells. Aiming to launch in North America in FY2015 and Japan in FY2016, DSP hopes to contribute to the treatment of cancer patients as soon as possible.

In addition, the title and the abstract of the presentation at ASCO were already disclosed on May 9, and May 16, 2013, respectively.

(Reference: about BBI608)

BBI608 is an orally-administered first-in-class anti-cancer drug created and currently under development by Boston Biomedical Inc. and was shown to inhibit the Stat3 pathways, Nanog pathways and β -catenin pathways in pre-clinical study. BBI608 is small molecule compound with a novel mechanism that blocks cancer stem cells (cancer cells with stem cell-like properties) self-renewal and induces cell death in CSC as well as other heterogeneous cancer cells. By targeting cancer stem cells in addition to heterogeneous cancer cells, efficacy is expected in the current challenges in therapy against cancer, such as treatment resistance, metastasis and recurrence.

Currently, the clinical studies below are in progress.

- Colorectal Cancer (monotherapy): Phase III in the U.S. and Canada
- Colorectal Cancer (combination therapy): Phase II in the U.S. and Canada
- Solid Cancer (combination therapy with paclitaxel): Phase I/II in the U.S. and Canada
- Solid Cancer (monotherapy): Phase I in Japan