January 23, 2017

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Announces Clinical Data of Investigational Cancer Stemness Inhibitor Napabucasin were presented at 2017 ASCO GI Symposium

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; President: Masayo Tada; "Sumitomo Dainippon Pharma") announced today that two poster presentations of napabucasin (BBI608) were delivered on January 21, 2017 (U.S. time) at the 2017 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium, January 19 to 21, 2017, in San Francisco.

Overview of poster presentations at the ASCO-GI

1. Results of Phase 1b/2 study of napabucasin with FOLFIRI, or FOLFIRI and bevacizumab administered to colorectal cancer patients. (BBI608-246:NCT02024607)

Abstract Number	593
Title	Cancer stemness inhibition and chemosensitization: Phase Ib/II study of cancer stemness inhibitor napabucasin (BBI608) with FOLFIRI +/- bevacizumab (Bev) administered to colorectal cancer (CRC) patients (pts)
Lead presenter	Johanna Bendell, Sarah Cannon Cancer Research Institute/Tennessee Oncology, Nashville, TN
Overview of the study result	63 CRC pts with an average of >2 prior therapy lines were enrolled. This phase Ib/II study suggests napabucasin may sensitize chemorefractory CRC to FOLFIRI +/- Bev and encouraging signs of synergistic activity was observed in CRC pts regardless of p-STAT3 status.
Safety	No pharmacokinetic interactions or dose-limiting toxicity was observed. Most common adverse events (AEs) included grade 1/2 diarrhea, nausea, vomiting and fatigue. 1 pt had grade 4 diarrhea and 27 pts had grade 3 AEs, including diarrhea (14), fatigue (4), dehydration (2), electrolyte imbalance (4), nausea (1), vomiting (1), abdominal pain (1) and weight loss (1), all of which resolved with dose reduction and supportive care.
Efficacy	Among 56 pts enrolled who received RECIST evaluation, disease control rate(DCR:CR+PR+SD) was observed in 88%(49 pts) with an overall response rate(ORR:CR+PR) of 29%(16 pts) with 1 pt achieving CR.

(Reference: DCR and ORR)

Subset	DCR		ORR	
	Evaluable	ITT	Evaluable	ITT
FOLFIRI naïve	93% (28/30)	82% (28/34)	33% (10/30)	29% (10/34)
FOLFIRI exposed	81% (21/26)	72% (21/29)	23% (6/26)	21% (6/29)
p-STAT3^{high}	84% (26/31)	79% (26/33)	26% (8/31)	24% (8/33)
p-STAT3^{low}	92% (23/25)	77% (23/30)	32% (8/25)	27% (8/30)

2. Results of Phase 1b/2 study of napabucasin with panitumumab administered to K-ras wild-type patients with metastatic colorectal cancer (BBI608-224: NCT01776307)

Abstract Number	677
Title	BBI608-224: A phase Ib/II study of cancer stemness inhibitor napabucasin (BBI608) administered with panitumumab in K-ras wild-type patients with metastatic colorectal cancer.
Lead presenter	Tim Larson, Minnesota Oncology, Minneapolis, MN
Overview of the study result	72 pts were enrolled, 48 pts were evaluable by RECIST of which 7 (15%) and 41 (85%) had 2 or ≥3 prior treatment lines, respectively. Of the 48 evaluable pts, 37 (77%) were previously treated with an anti-EGFR agent. Napabucasin was safely combined with panitumumab at full dose with no unexpected adverse events and no evidence of pharmacological interaction. Encouraging anti-tumor activity in pts with K-ras, wt mCRC was observed. Napabucasin may sensitize pts to repeat anti-EGFR therapy.
Safety	The safety profile was consistent with that of each agent as monotherapy and most common AEs included grade 1/2 diarrhea, nausea, abdominal cramps, and vomiting.
Efficacy	Among 48 pts enrolled who received RECIST evaluation, Disease Control Rate (DCR) was observed in 54.2%(26 pts) of which 2 pts achieved PR (4%) and 24 pts achieved SD (50%). Among 37 pts previously treated with anti-EGFR therapy, DCR was observed in 54%(20 pts) compared with DCR of 54.5% observed in 6 out of 11 anti-EGFR naïve pts receiving a scan.

(Reference: mPFS and mOS)

Population	Subgroup	mPFS (months)	mOS (months)
ITT	Anti-EGFR^{Naïve} n=18	3	13.3
	Anti-EGFR^{Exposed} n=54	2.1	9.1
	Total n=72	2.1	9.1

Evaluable	Anti-EGFR^{Naïve} n=11	3.9	17.9
	Anti-EGFR^{Exposed} n=37	2.6	9.9
	Total n=48	3	12.2

(Reference)

About napabucasin (BBI608)

Napabucasin is an investigational first-in-class anti-cancer agent created and currently under development by Boston Biomedical, Inc. Napabucasin is an orally-administered small molecule agent designed to inhibit cancer stemness pathways by targeting STAT3.

Contact:
Public Relations/Investor Relations
Sumitomo Dainippon Pharma Co., Ltd.
TEL: +81-6-6203-1407(Osaka)
+81-3-5159-3300 (Tokyo)