October 6, 2016
Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma announces the final data analysis of a global phase 3 study of an investigational anti-cancer drug Napabucasin (CO.23 study) will be presented at the ESMO 2016 Congress

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; President: Masayo Tada; hereinafter called "Sumitomo Dainippon Pharma") announced today that the final data analysis of CO.23 study will be presented by the sponsor of CO.23 study, CCTG et al., at the ESMO 2016 Congress in Copenhagen, Denmark from October 7 to 11, 2016. The abstract is now available on the official website of ESMO.
https://cslide.ctimeetingtech.com/library/esmo/browse/search/5PW#2z95s0Mb
Outlines of the session follow:
In addition, as previously disclosed, on May 23, 2014, the CO.23 study closed to accrual and protocol treatment stopped in May, 2014.

【Scheduled Presentation at ESMO 2016】
Date and Time: Sunday, October 9, 2016,
3:36 PM – 3:48 PM (local time)
Abstract Number: 2620
Session: Proffered Paper session (oral presentation)
Location: Vienna

【Title】
A randomized phase III study of napabucasin [BBI608] (NAPA) vs placebo (PBO) in patients (pts) with pretreated advanced colorectal cancer (ACRC): The CCTG/AGITG CO.23 trial

【Presenter】
D.J. Jonker
(Department of Medicine, Division of Medical Oncology, Ottawa Hospital Research Institute, University of Ottawa)

【Highlights of the abstract】
282 patients were randomized (138 napabucasin, 144 placebo) from 04/2013 - 05/2014 when the trial was unblinded, accrual closed, and protocol treatment stopped after the futility analysis. Pts were median age=64 (32 to 85); male=65%;ECOG Performance Status 0:1 (%) =28:72; >4 prior regimens=98%; prior anti-VEGF=89%; KRAS WT=52%. No significant difference was observed in OS, progression free survival (PFS) or DCR between NAPA and PBO in the ITT analysis.
AE more frequent with NAPA included: any grade diarrhea (88 vs 32%), nausea (63 vs 47%), and anorexia (56 vs 46%), all $p<0.05$; at least one AE ≥ grade 3 (57% vs 40%, $p<0.01$) with

grade 3 (no grade 4) diarrhea (17% vs 1%, p<0.01). Diarrhea was reversible upon NAPA hold. EORTC QLQ-C30 physical function at 8 Weeks deteriorated in 49% of pts on NAPA vs 29% on PBO (p=0.038).

Of 251 (89%) pts with p-STAT3 data, 55 (22%) were positive. In pts on PBO, p-STAT3 positivity was a poor prognostic factor (median OS 3.0 vs 4.9 mo, HR 2.3 [95% CI 1.5 - 3.6], p=0.0002), but NAPA improved OS in p-STAT3 positive pts, HR 0.24.

Subset	Median OS (mos)		HR[95%CI], p value
	PBO	NAPA	
ITT			
All Pts (n=282)	4.8	4.4	1.13 [0.88 - 1.46],p=0.34
p-STAT3 + (n=55)	3.0	5.1	0.24 [0.12 - 0.51],p=0.0002*
p-STAT3 - (n=196)	4.9	4.0	1.44 [1.06 - 1.95]p=0.02*
Pre-defined Minimum Effective Treatment			
All Pts (n=128)	5.8	6.6	0.88 [0.61 - 1.28],p=0.50
p-STAT3 + (n=25)	4.0	9.0	0.28 [0.11 - 0.69],p=0.0057[a]
p-STAT3 - (n=88)	6.4	6.4	1.27 [0.80 – 2.01], p=0.32[a]
*adjusted interaction	HR 0.28 [0.14-0.55],		p<0.0001
[a]adjusted interaction	HR 0.22 [0.08-0.61],		p=0.0038

Note1: “Pre-defined Minimum Effective Treatment” means patients who received ≥50% total daily dose for ≥6.4 weeks

Note2: This abstract was submitted by CCTG, the sponsor of the CO.23 study.

(Reference)

About napabucasin (BBI608)

Napabucasin is an investigational first-in-class anti-cancer drug created and currently under development by Boston Biomedical, Inc. Napabucasin is an orally administered small molecule agent that targets STAT3, leading to inhibition of the critical genes for maintaining cancer stemness.

About the CO.23 study

CO.23 is a randomized phase 3 study of napabucasin (BBI-608) versus placebo in patients with pretreated advanced colorectal cancer (CRC) who had failed all standard therapeutics. CCTG is a sponsor and retains the publication right of the data of the CO.23 study. As previously disclosed, on May 23, 2014, the protocol-defined first interim analysis of the initial 97 patients enrolled into its CO.23 study has been completed and DSMC recommended that further enrollment of new patients be stopped and all study drug be discontinued because while there is no safety concern, the futility analysis, based on disease control rate, met protocol defined criteria for stopping.

About CCTG (Canadian Cancer Trials Group; previously known as NCIC-CTG)
CCTG is a cooperative oncology group which carries out clinical trials in cancer therapy, supportive care and prevention across Canada and internationally. It is one of the national programs and networks of the Canadian Cancer Society Research Institute (CCSRI), and is supported by the Canadian Cancer Society (CCS).

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