

Press Release

Boston Biomedical's Investigational Cancer Stem Cell Pathway Inhibitor, Napabucasin (BBI608), Featured at the ASCO 2016 Gastrointestinal Cancers Symposium

CAMBRIDGE, Mass. January 25, 2016 – [Boston Biomedical](#), an industry leader in the development of novel compounds designed to target cancer stem cell (CSC) pathways, announced that three poster presentations were highlighted at the 2016 Gastrointestinal Cancers Symposium, held by the American Society of Clinical Oncology (ASCO), January 21 to 23, 2016, in San Francisco.

“We were pleased to share these data from napabucasin (BBI608) in advanced and difficult-to-treat tumor types at this year’s ASCO Gastrointestinal Cancers Symposium,” said Chiang J. Li, M.D. FACP, the President, CEO and Chief Medical Officer of Boston Biomedical, and the Head of Global Oncology for Sumitomo Dainippon Pharma Group. “These studies continue to show napabucasin’s safety and early efficacy across doses and in combination with a variety of established agents. We plan to apply these findings as we advance and expand our clinical development program for this first-in-category cancer stemness inhibitor.”

Data presented at the symposium support the continued development of the investigational cancer stemness inhibitor napabucasin (also known as BBI608, BB608 or BBI-608) — an orally-administered agent designed to inhibit cancer stem cell pathways by targeting the STAT3 pathway — for anti-cancer activity when used in combination with other agents across advanced, pretreated and untreated metastatic pancreatic cancers, as well as advanced, pretreated colorectal cancer.

“These clinical studies of napabucasin in advanced gastroenterological cancers, including the presentation of data in refractory colorectal cancer specifically, show encouraging clinical activity by targeting cancer stem cell pathways that contribute to cancer recurrence, metastases and resistance to therapies,” commented Axel Grothey, M.D., professor of oncology, Mayo Clinic. “I look forward to the further investigation of this innovative approach to cancer treatment in additional clinical studies.”

Overview of the Boston Biomedical poster presentations:

- [Abstract #284 \(NCT02231723\)](#), [Poster Session B Board #E8: A Phase Ib study of Cancer Stem Cell \(CSC\) pathway inhibitor Napabucasin \(BBI608\) in combination with Gemcitabine and nab-Paclitaxel \(nab-PTX\) in patients \(pts\) with metastatic pancreatic ductal adenocarcinoma \(mPDAC\)](#) [Safi Shahda, M.D., IU Health University Hospital]
 - Data from this phase Ib study demonstrate that napabucasin (BBI608) at 240 mg twice daily was combined with gemcitabine and nab-paclitaxel, resulting in early anti-tumor activity in patients with metastatic pancreatic ductal adenocarcinoma.

Of the 31 patients enrolled, 25 patients were treatment-naïve and 6 patients had received one prior line of systemic therapy in the adjuvant setting only. Safety data was available for 18 patients and efficacy data was available for 8 patients at clinical cut off for abstract submission for the 8-patient cohort of recommended phase II dose determination. Safety and efficacy data for the rest of the patients are being followed.

Of the 8 patients enrolled to determine the recommended phase II dose, 7 patients were evaluable for response and 100% had partial response (PR) or stable disease (SD). Tumor regression was observed in 6/7 patients (85.7%) with 3 PR (41.3%, 37.1% and 33.3% regression) and 3 SD (25.8%, 21.1%, and 20.5% regression). Six of 7 evaluable patients (85.7%) had prolonged PR or SD of 24 weeks or longer.

The most common adverse events included grade 1 diarrhea, nausea, fatigue, abdominal pain and anorexia.

- **[Abstract #196 \(NCT01325441\)](#), [Poster Session B Board #A6](#): Phase Ib/II Study of Napabucasin (BBI608) combined with Weekly Paclitaxel in Advanced Pancreatic Cancer [Tanios Bekaii-Saab, M.D., Ohio State University Wexner Medical Center]**
 - Results from this phase Ib/II extension study of napabucasin (BBI608) at 480 mg twice daily plus weekly paclitaxel showed early anti-cancer activity in patients with refractory, heavily pretreated pancreatic cancer, particularly in taxane-naïve patients. Durable disease control and prolonged overall survival in this study patient population were also observed.

The 41 patients enrolled had received a median of two prior lines of treatment including FOLFIRINOX (71%), gemcitabine/nab-paclitaxel (44%) or both (37%).

The 31 evaluable patients had a response rate (partial response, PR + complete response, CR) of 6% and disease control rate (stable disease, SD + PR + CR) of 48%. The 19 evaluable taxane-naïve patients had a response rate of 11% and disease control rate of 63%, and 16% were progression-free at 24 weeks. Overall for the 41 patients, median progression-free survival (mPFS) was 2.2 months and median overall survival (mOS) was 6.0 months, while the 23 taxane-naïve patients demonstrated mPFS of 3.9 months and mOS of 7.4 months.

The most common adverse events included grade 1 and 2 diarrhea, fatigue and abdominal pain, and grade 1 nausea, anorexia and vomiting.

- **[Abstract #569 \(NCT02024607\)](#), [Poster Session C Board #D18](#): A Phase Ib study of first-in-class cancer stemness inhibitor Napabucasin (BBI608) in combination with FOLFIRI with and without Bevacizumab in Patients with Advanced Colorectal Cancer [Joleen Hubbard, M.D., Mayo Clinic]**
 - This phase Ib study showed that napabucasin (BBI608) at 240 mg twice daily can be combined with FOLFIRI with and without bevacizumab, and demonstrated early anti-tumor activity in heavily pretreated colorectal cancer patients, even in those with prior progression on FOLFIRI-based therapy.

Of the 18 enrolled heavily pretreated patients (average of >3 prior lines of therapy), 10 patients previously progressed on FOLFIRI. Of the 17 evaluable patients, 8 patients received FOLFIRI and 9 received FOLFIRI with bevacizumab, both in combination with napabucasin.

Disease control (partial response, PR + stable disease, SD) was observed in 94% of evaluable patients (16 of 17). Ten evaluable patients (59%) achieved prolonged disease control (PR and SD) of 24 weeks or more.

The most common adverse events included grade 1 and 2 diarrhea, fatigue, nausea, vomiting, abdominal pain and anorexia; no dose limiting toxicity or new adverse events were seen and the safety profile was similar to that of each regimen as monotherapy.

The full posters of the above studies are available on the [R&D publications](#) page of the Boston Biomedical [website](#).

About Boston Biomedical

Boston Biomedical, Inc. (Founder, President, CEO and CMO: Chiang J. Li, M.D. FACP) was founded in November 2006 and is wholly owned by Sumitomo Dainippon Pharma Co., Ltd. Boston Biomedical's mission is to develop the next generation of cancer therapeutics by creating drugs designed to target cancer stem cell pathways. Boston Biomedical's innovation in drug discovery has received a number of recognitions and awards in the United States, including the Frost & Sullivan 2010 North American Drug Discovery Technology Innovation of the Year Award, the National Cancer Institute (NCI) cancer stem cell initiative grant award in 2010, and the 2011 Biotech Pioneer Award at the Alexandria Oncology Summit. The company also received the "Company To Watch" award in the 10th Annual Team Massachusetts Economic Impact Awards in 2013. Boston Biomedical is headquartered in Cambridge, Massachusetts, USA.

Additional information about the company and its product pipeline can be found at www.bostonbiomedical.com.

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