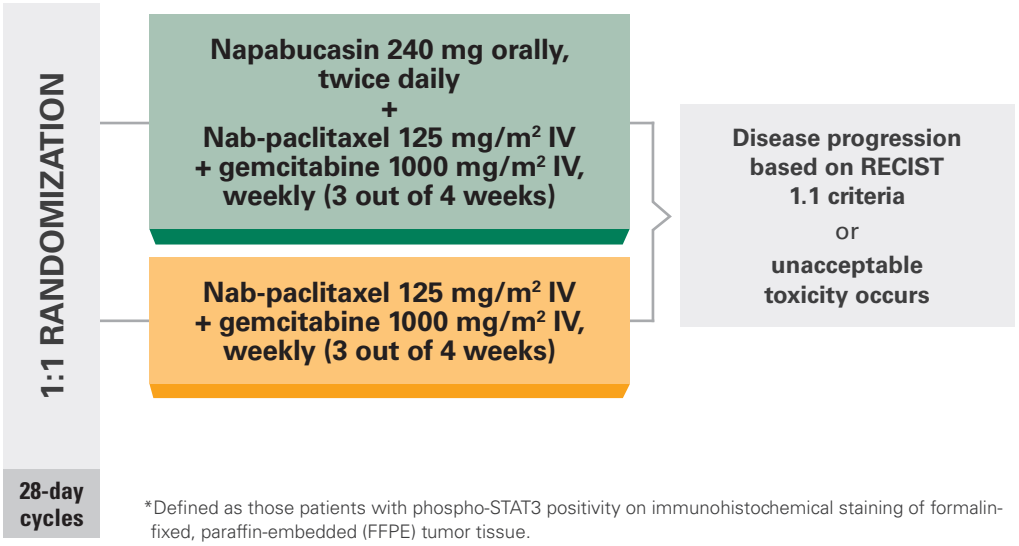
PHASE III

The CanStem 111P Trial

A Trial of Napabucasin (BBI-608) Plus Weekly Nab-paclitaxel With Gemcitabine in Adult Patients With Metastatic Pancreatic Ductal Adenocarcinoma (PDAC)



Primary Endpoint
- Overall survival (OS)

Secondary Endpoints
- OS in biomarker-positive* patients
- Progression-free survival (PFS)
- PFS in biomarker-positive* patients
- Overall response rate (ORR) and disease control rate (DCR)
- ORR and DCR in biomarker-positive* patients
- Quality of life
- Safety

*Defined as those patients with phospho-STAT3 positivity on immunohistochemical staining of formalin-fixed, paraffin-embedded (FFPE) tumor tissue.

Key Inclusion Criteria

- Age ≥18 years
- ECOG PS 0 or 1
- Life expectancy >12 weeks
- Histologically or cytologically confirmed metastatic PDAC
- Not received chemotherapy or any investigational agent for the treatment of PDAC
- Nab-paclitaxel with gemcitabine therapy is appropriate for the patient and recommended by the Investigator

Study Locations

Global sites in Asia, North America, and Europe, including Japan and the US, are actively recruiting. Please check www.clinicaltrials.gov for updates about this study (NCT02993731) and for a listing of clinical study site locations.

About Napabucasin

Napabucasin is an investigational, orally administered agent hypothesized to inhibit cancer stemness pathways, and has not yet been approved by the FDA or any other health authorities.

See ClinicalTrials.gov for comprehensive eligibility criteria.

IV=intravenously; RECIST 1.1=Response Evaluation Criteria in Solid Tumors version 1.1; ECOG PS=Eastern Cooperative Oncology Group Performance Status.

Boston Biomedical, Inc. is a leading developer of next-generation cancer therapeutics designed to inhibit cancer stemness pathways and modify immune responses.

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www.bostonbiomedical.com

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