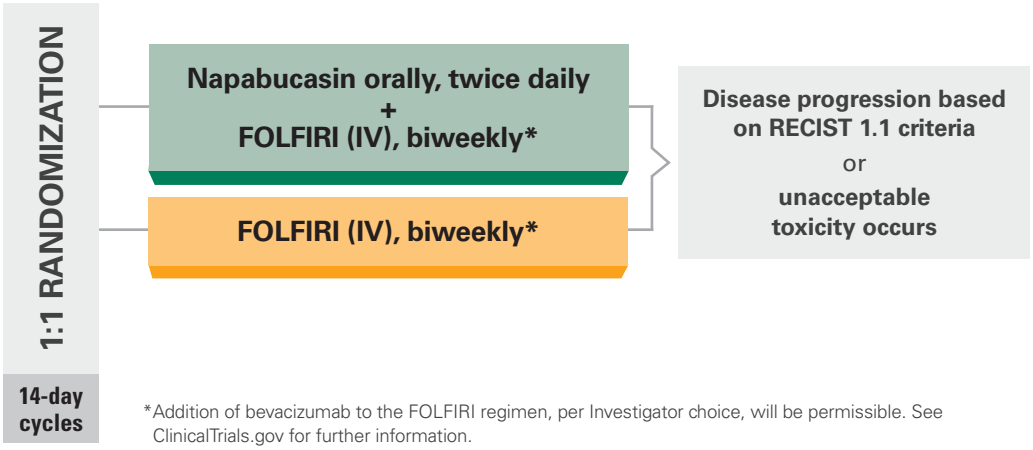
The CanStem 303C Trial

PHASE III

A Trial of Napabucasin (BBI-608) in Combination With FOLFIRI in Adult Patients With Previously Treated Metastatic Colorectal Cancer (mCRC)



*Addition of bevacizumab to the FOLFIRI regimen, per Investigator choice, will be permissible. See ClinicalTrials.gov for further information.

Primary Endpoint
- Overall survival

Secondary Endpoints
- Progression-free survival
- Objective response rate and disease control rate
- Quality of life
- Safety

Key Inclusion Criteria

- Age ≥18 years
- ECOG PS 0 or 1
- Histologically confirmed adenocarcinoma of the colon or rectum that is metastatic
- Failed treatment with a minimum of 6 weeks of first-line combination therapy for metastatic disease that included bevacizumab (if applicable), oxaliplatin, and a fluoropyrimidine in the same cycle. Treatment failure is defined as radiologic progression during or <6 months after the last dose of first-line treatment
- FOLFIRI therapy is appropriate for the patient and is 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 (NCT02753127) 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.

FOLFIRI=5-fluorouracil 400 mg/m^2 bolus followed by 1200 mg/m^2/day continuous infusion, leucovorin 400 mg/m^2, and irinotecan 180 mg/m^2; 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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