



Boundless Bio Announces Clinical Trial Collaboration and Supply Agreement with Taiho Oncology to Evaluate LYTGOBI® (futibatinib) in Combination with BBI-355 in Patients with FGFR Amplified Solid Tumors

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Combination of BBI-355 and futibatinib to be evaluated in Boundless Bio's ongoing Phase 1/2 clinical trial (POTENTIATE) in patients with FGFR amplifications

SAN DIEGO--([BUSINESS WIRE](#))--[Boundless Bio](#), a clinical stage, next-generation precision oncology company interrogating extrachromosomal DNA (ecDNA) biology to deliver transformative therapies to patients with previously intractable oncogene amplified cancers, today announced that it has entered into a clinical trial collaboration and supply agreement with Taiho Oncology, Inc. (Taiho) for Taiho's pan-FGFR inhibitor LYTGOBI® (futibatinib) for use in combination with BBI-355 in a clinical trial of patients with locally advanced or metastatic solid tumors with oncogene amplifications. BBI-355 is an orally administered, novel, selective small molecule inhibitor of CHK1 and represents what Boundless Bio believes is the first ecDNA-directed therapy (ecDTx) in development for oncogene amplified cancers.

"This clinical trial collaboration and supply agreement with Taiho marks an important step in the continued execution of our clinical strategy and the next step in realizing the transformative potential of BBI-355, which we believe is the first ecDNA-directed therapy in development for patients with cancer that harbor oncogene amplifications on ecDNA," said Zachary Hornby, President and Chief Executive Officer of Boundless Bio. "FGFR inhibitors given as monotherapy have to date demonstrated less clinical benefit in patients with cancer harboring FGFR amplifications than in patients with other FGFR driver alteration types. We believe that BBI-355, when combined with Taiho's futibatinib, has the potential to demonstrate meaningful anti-tumor activity for patients with cancer and FGFR amplifications. We look forward to assessing this novel combination in our ongoing Phase 1/2 POTENTIATE trial."

Under the terms of the agreement, Taiho will provide futibatinib clinical drug supply at no cost for Boundless Bio's ongoing Phase 1/2 clinical trial (POTENTIATE), which will assess BBI-355 in combination with certain selected targeted therapies, including futibatinib, in patients with specific oncogene amplified solid tumors.

About the POTENTIATE Trial

BBI-355 is being evaluated in a first-in-human Phase 1/2 clinical trial ("POTENTIATE": Precision Oncology Trial Evaluating Novel Therapeutic Interrupting Amplifications Tied to ecDNA) in patients with locally advanced or metastatic solid tumors with oncogene amplifications, whose disease has progressed despite all standard therapies or for whom no further standard or clinically acceptable therapy exists.

The open-label, non-randomized, 3-part trial involves: BBI-355 single agent dose escalation and expansion in cancer patients with oncogene amplification, dose escalation of BBI-355 in combination with certain selected targeted therapies in cancer patients with specific oncogene amplifications, and dose expansion of BBI-355 in combination with certain selected targeted therapies in cancer patients with specific oncogene amplification on ecDNA. BBI-355 is administered orally every other day. In part 3 of the trial, an ecDNA diagnostic clinical trial assay (CTA), which we call ECHO (ecDNA Harboring Oncogenes), will be implemented to determine the presence of oncogenes amplified on ecDNA in patient tumor samples. ECHO is a proprietary bioinformatic diagnostic algorithm designed by Boundless Bio and developed into a CTA in collaboration with SOPHiA GENETICS to detect oncogenes amplified on ecDNA from tumor biopsy samples using routine clinical NGS assays.

About BBI-355

BBI-355 is an orally administered, novel, selective checkpoint kinase 1 (CHK1) inhibitor and, what we believe, is the first ecDNA-directed therapy (ecDTx) being investigated to treat patients with oncogene amplified cancer. CHK1 is a master regulator of the cellular response to DNA replication stress (RS), which frequently arises from oncogene amplification on ecDNA. By disrupting proper CHK1 function in oncogene amplified cancer cells, we believe BBI-355 facilitates catastrophic RS, and preferentially kills cancer cells relative to healthy cells. CHK1 was identified as an ecDNA essential target via Boundless Bio's proprietary Spyglass research platform.

About Boundless Bio

Boundless Bio is a clinical stage, next-generation precision oncology company dedicated to the discovery and development of new drugs targeting a novel area of cancer biology, extrachromosomal DNA (ecDNA), to deliver transformative therapies intended to improve and extend the lives of patients with oncogene amplified cancers. Boundless Bio is developing what it believes is the first ecDNA-directed therapy (ecDTx), BBI-355, which is being evaluated in a Phase 1/2 clinical trial and has multiple other pipeline programs advancing in preclinical development and discovery. To date, Boundless Bio has raised more than \$250 million from leading life sciences investors.

For more information, visit www.boundlessbio.com.

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Lytgobi® is a registered trademark of Taiho Pharmaceutical Co., Ltd.

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