Boundless Bio Announces Portfolio Prioritization and Runway Extension

May 23, 2025

Portfolio prioritization focuses on novel-novel combination therapy of BBI-355 and BBI-825 and new development candidate, BBI-940, for novel kinesin program

Operating runway extended into the first half of 2028, through expected proof-of-concept clinical readouts for each program

Conference call and webcast to be held Tuesday, May 27 at 8:00 am ET

SAN DIEGO, May 23, 2025 (GLOBE NEWSWIRE) -- Boundless Bio (Nasdaq: BOLD), a clinical-stage oncology company interrogating extrachromosomal DNA (ecDNA) biology to deliver transformative therapies to patients with previously intractable oncogene amplified cancers, today provided business updates focused on optimizing the Company's portfolio for patient impact and long-term value-creation.

Executive Summary

- Discontinuing current monotherapy and combination arms of BBI-355 in POTENTIATE clinical trial.
- Plans to evaluate BBI-355 and BBI-825 as a combination therapy in the POTENTIATE clinical trial, targeting initiation in the second half of 2025.
- Declared BBI-940 as the development candidate for novel Kinesin program; IND submission on track for the first half of 2026.
- Streamlined operations, extending the Company's expected cash runway into the first half of 2028, through proof-of-concept clinical milestones for each of its therapeutic programs.

"At Boundless, we're committed to delivering innovative therapies for patients with oncogene-amplified cancers through disciplined execution," said Zachary Hornby, President and Chief Executive Officer of Boundless Bio. "By prioritizing the novel combination of BBI-355 and BBI-825, along with our exciting Kinesin program, BBI-940, we're concentrating our resources where we see the greatest potential to develop meaningful medicines. These decisions extend our operating runway into the first half of 2028, which should enable us to reach initial clinical milestones for these programs with our current capital."

BBI-355 and BBI-825 Programs

Discontinuing current monotherapy and combination arms of BBI-355 in POTENTIATE clinical trial

Boundless has been investigating BBI-355, a novel, oral, selective CHK1 inhibitor designed to target replication stress in oncogene-amplified cancers in its ongoing Phase 1/2 POTENTIATE clinical trial. In the trial, which explored different dose levels and dosing regimens, BBI-355 has demonstrated a narrow therapeutic index with continuous every other day dosing (Q2D), resulting from hematological toxicity at or near doses associated with clinical activity. The Company believes BBI-355's narrow therapeutic index makes it suboptimal for continued development as a single agent with continuous dosing. In addition, the combinations of BBI-355 with the EGFR inhibitor erlotinib, and with the FGFR inhibitor futibatinib, were not well-tolerated with Q2D dosing at the exposure levels believed to be required for robust, sustained anti-tumor activity. Based on these findings and market considerations, the Company has decided to discontinue further clinical development in the current arms of the POTENTIATE clinical trial.

Pursuing novel-novel combination for BBI-355 and BBI-825

Last year, Boundless announced its decision to not advance the STARMAP clinical trial of its novel, oral, selective ribonucleotide reductase (RNR) inhibitor, BBI-825. The decision was due, in part, to a lack of dose proportional pharmacokinetic exposure observed at steady-state as a result of BBI-825 inducing its own metabolism in trial subjects following continuous twice daily (BID) dosing. Based on recent studies, the Company believes that there is strong mechanistic rationale to combine BBI-825 with BBI-355 for synergistic anti-tumor activity as a replication stress combination therapy that does not require continuous dosing, nor involve overlapping toxicity. The novel/novel combination demonstrated preclinical evidence of synergistic cytotoxicity in cancer cell lines and tumor regression in mouse xenograft models using weekly dosing at exposures not associated with hematologic toxicity. The company will present additional scientific details supporting this decision during the live webcast on Tuesday, May 27.

Boundless plans to initiate clinical development of the BBI-355/BBI-825 combination in 2025 and expects to deliver initial proof-of-concept clinical data within its extended cash runway timeline.

Kinesin Program

Development candidate BBI-940 declared for novel Kinesin program

Boundless's novel Kinesin program targets a previously undrugged kinesin involved in DNA segregation, including ecDNA segregation, during mitosis. The Company has discovered orally bioavailable, highly selective Kinesin degraders that have demonstrated potent anti-tumor activity in a range of cancer cell lines as well as single agent tumor regressions in mouse xenograft cancer models. The Company selected BBI-940 as its development candidate and reaffirmed that it expects to submit an Investigational New Drug (IND) application in the first half of 2026. Boundless expects to deliver initial proof-of-concept clinical data from BBI-940 within its extended cash runway timeline.

Operational Update

In connection with its portfolio prioritization, Boundless has streamlined its operations, resulting in an approximately one-third reduction of its workforce. The Company believes the combination of portfolio prioritization, streamlined operations, and its cash, cash equivalents, and short-term

investments of $138.3 million as of March 31, 2025, will extend its operating runway into the first half of 2028 and through anticipated clinical proof-of-concept readouts for each of its therapeutic programs.

Mr. Hornby concluded, “I want to personally thank our departing team members, whose valuable contributions have helped advance our science and build our company. Their work remains an integral part of our foundation as we continue our important mission for patients.”

Webcast and Conference Call Information

Boundless will host a live webcast and conference call on Tuesday, May 27 at 8:00 am ET to discuss these updates. To access the webcast and slides, please visit Events & Presentations in the Investors section of the Company’s website at boundlessbio.com. A replay of the webcast will be available for 30 days following the event.

About Boundless Bio

Boundless Bio is a clinical-stage oncology company dedicated to unlocking a new paradigm in cancer therapeutics to address the significant unmet need of patients with oncogene amplified tumors. Boundless Bio’s research focuses on extrachromosomal DNA (ecDNA), a root cause of oncogene amplification observed in 14% to 17% of cancer patients. Boundless Bio is developing the first ecDNA-directed therapeutic candidate (ecDTx), BBI-355, which is an oral inhibitor of checkpoint kinase 1 (CHK1) being evaluated in a Phase 1/2 clinical trial in patients with oncogene amplified cancers. Boundless Bio’s next ecDTx, BBI-825, is an oral inhibitor of ribonucleotide reductase (RNR) that has been evaluated in a Phase 1/2 clinical trial in cancer patients with resistance gene amplifications. Boundless Bio is also conducting IND-enabling studies of BBI-940, a potentially first-in-class orally bioavailable, highly selective Kinesin degrader. Boundless Bio is headquartered in San Diego, CA. For more information, visit www.boundlessbio.com and follow us on LinkedIn and X.

Forward-Looking Statements

Boundless Bio cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on our current beliefs and expectations and include but are not limited to: our expected cash runway and the sufficiency thereof to fund operations through anticipated proof-of-concept clinical data readouts for each of our therapeutic programs; the timing of expected data readouts; submission of an IND application for BBI-940 and the timing thereof; our plans to discontinue the current arms of the POTENTIATE trial; the expected benefits of our portfolio prioritization; and the potential safety and therapeutic benefits of our ecDTx in treating patients with oncogene amplified cancers. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: we are early in our development efforts and our approach to discover and develop ecDTx to treat oncogene amplified cancers is novel and unproven; results from preclinical studies or early clinical trials not necessarily being predictive of future results; potential delays in the commencement, enrollment, data readouts or completion of clinical trials or preclinical studies or submission of an IND, including as a result of FDA feedback on our regulatory submission to support our planned clinical trial of the BBI-355 and BBI-825 combination; we may not realize the benefits expected from our portfolio prioritization and the streamlining of operations and workforce reduction, including our ability to conserve cash; our ability to retain remaining key personnel; our dependence on third parties in connection with clinical trials, preclinical studies, and manufacturing; unfavorable results from clinical trials or preclinical studies; we may expend our limited resources to pursue a particular ecDTx or combination therapy and fail to capitalize on ecDTx with greater development or commercial potential; unexpected adverse side effects or inadequate efficacy of our ecDTx that may limit their development, regulatory approval, and/or commercialization; the potential for our programs and prospects to be negatively impacted by developments relating to our competitors, including the results of studies or regulatory determinations relating to our competitors; regulatory developments in the United States and foreign countries; we may use our capital resources sooner than we expect; and other risks described in our filings with the Securities and Exchange Commission (SEC), including under the heading “Risk Factors” in our annual report on Form 10-K for the year ended December 31, 2024 and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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