Boundless Bio Announces Pipeline and Leadership Updates

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Company elects not to advance BBI-825 into Part 2 portion of STARMAP clinical trial

Third ecDTx program advancing, with plans for development candidate nomination by mid-2025

Operating runway extended into 2027, through anticipated clinical readout for BBI-355 and key development milestones for third ecDTx program

Klaus Wagner, M.D., Ph.D., Chief Medical Officer, and Neil Abdollahian, Chief Business Officer, stepping down; James L. Freddo, M.D., to serve as Interim Chief Medical Officer

SAN DIEGO, Dec. 12, 2024 (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 announced updates to its portfolio of ecDNA directed therapy (ecDTx) programs and to its executive leadership team.

Pipeline Updates
Boundless announced the following updates to its portfolio of novel ecDTx programs for a range of aggressive and difficult-to-treat cancer indications:

- **Initial clinical data readout for BBI-355 on track for the second half of 2025**: Enrollment is ongoing in Boundless's Phase 1/2 POTENTIATE clinical trial, which is evaluating BBI-355 both as a single agent and in combination with targeted therapies for patients with oncogene-amplified solid tumors. BBI-355 is a novel, oral, and potent CHK1 inhibitor specifically designed to target replication stress in oncogene-amplified cancers. The company has reaffirmed its expectation to report preliminary clinical proof-of-concept safety and antitumor activity data in the second half of 2025.
- **Decision not to advance BBI-825 into Part 2 portion of STARMAP trial**: Boundless has been evaluating BBI-825, an oral RNR inhibitor, in the Phase 1/2 STARMAP clinical trial for patients with solid tumors, including those with *BRAF*^{V600E} or *KRAS*^{G12C} mutated colorectal cancer that has developed resistance oncogene amplifications. To date, BBI-825 has been generally well-tolerated. Following an assessment of preliminary pharmacokinetic data from the Part 1 portion of the trial showing a lack of dose-proportional exposure, and the increasing complexity and associated development costs related to the evolving *BRAF*^{V600E} and *KRAS*^{G12C} mutated cancer treatment landscape, Boundless has made the strategic decision not to continue dose escalation of Part 1 or to proceed into the Part 2 portion of the STARMAP trial.
- **Third ecDTx program advances, with development candidate nomination expected by mid-2025:** Boundless has progressed its ecDTx 3 program targeting a previously undrugged kinesin essential for ecDNA segregation and expects to select a development candidate by mid-2025. The company has reaffirmed that it expects to submit an Investigational New Drug (IND) application in the first half of 2026.

Leadership Transitions
Boundless also announced that Klaus Wagner, M.D., Ph.D., Chief Medical Officer (CMO), and Neil Abdollahian, Chief Business Officer (CBO), will depart the company at the end of December and in early January, respectively. James L. Freddo, M.D., current advisor to Boundless with nearly 30 years of clinical leadership experience in biopharmaceutical companies, will serve as Interim CMO while the company conducts a search for a permanent hire. Dr. Freddo's extensive background includes serving as CMO and later as a member of the board of directors at Ignyta, Inc., CMO and Senior Vice President, Development at Anadys Pharmaceuticals, and Vice President, Clinical Development, Oncology at Pfizer. Boundless does not intend to appoint a new CBO at this time.

"After a thorough assessment of BBI-825's emerging clinical data and anticipated development costs, particularly amid the dynamic and increasingly competitive landscape of *BRAF*^{V600E} and *KRAS*^{G12C}-mutated cancer treatment, we have decided not to advance the STARMAP trial. We are grateful to our team members, patients, and investigators who contributed to the BBI-825 program," said Zachary Hornby, President and CEO of Boundless Bio. "With this strategic decision, we are prioritizing resource allocation to BBI-355, which remains on-track for initial clinical proof-of-concept data in 2025, and our novel ecDTx 3 program, where we've made substantial preclinical progress and expect to nominate a development candidate by mid-2025. It also extends our operating runway into 2027, well beyond the anticipated milestones for both BBI-355 and ecDTx 3."

Mr. Hornby added, "At Boundless, we are seeking to improve outcomes for high unmet need oncogene amplified cancer patients by tackling complex challenges in cancer biology. I would like to sincerely thank both Klaus and Neil for their instrumental contributions to that work over the past several years and wish them well as they move to their next professional chapters. Looking ahead, we remain diligently focused on delivering meaningful outcomes for patients and other stakeholders and look forward to reporting on our progress in 2025."

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 by targeting extrachromosomal DNA (ecDNA), a root cause of oncogene amplification observed in more than 14% 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 second 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. Leveraging its Spyglass platform, Boundless Bio has additional programs advancing through preclinical development and discovery. 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: the timing of

expected data readout for the Phase 1/2 POTENTIATE clinical trial, and new development candidate nomination and submission of an IND application for ecDTx 3; the sufficiency of our cash position to fund operations through anticipated initial clinical proof-of-concept data readout for the Phase 1/2 POTENTIATE clinical trial, nomination of a new development candidate and submission of an IND application for a new development candidate for ecDTx 3 and into 2027; the company's plan to not advance the BBI-825 program; 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 directed against ecDNA in oncogene amplified cancers is novel and unproven; results from preclinical studies or early clinical trials not necessarily being predictive of future results; analytical validation of an ecDNA diagnostic not necessarily being predictive of its clinical validity and utility; potential delays in the commencement, enrollment, data readouts or completion of clinical trials or preclinical studies or submission of an IND; potential difficulty or delay in transitioning the CMO position and any resulting adverse impacts on our development programs or otherwise; our dependence on third parties in connection with clinical trials, preclinical studies, ecDNA diagnostic development, and manufacturing; unfavorable results from clinical trials or preclinical studies; we may expend our limited resources to pursue a particular ecDTx 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; efforts to streamline operations may not produce the efficiencies expected; 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 quarterly report on Form 10-Q for the quarter ended March 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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