Bolt Biotherapeutics Presents Results from the Phase 1 Dose-Escalation Clinical Study of BDC-3042 at AACR Annual Meeting 2025

April 25, 2025

BDC-3042 was well tolerated up to 10 mg/kg q2w with no dose-limiting toxicities and no drug-related serious adverse events

BDC-3042 showed biological activity, with clear dose-dependent increases in proinflammatory cytokines and chemokines

BDC-3042 showed signs of anti-tumor activity, including an unconfirmed partial response, stable disease ≥ 12 weeks in 3/3 non-small cell lung cancer patients and in 2/3 patients at the highest dose

Bolt is running a partnering process to advance development of BDC-3042

REDWOOD CITY, Calif., April 25, 2025 (GLOBE NEWSWIRE) -- Bolt Biotherapeutics (Nasdaq: BOLT), a clinical-stage biopharmaceutical company developing novel immunotherapies for the treatment of cancer, today announced results from its Phase 1 dose-escalation clinical study of BDC-3042 at the American Association for Cancer Research (AACR) Annual Meeting, taking place April 25-30, 2025, in Chicago, Illinois.

“We are excited about the potential of BDC-3042 to help patients with cancer. This initial dose-escalation study demonstrated a favorable safety profile, dose-dependent biologic activity, and monotherapy anti-tumor activity,” said Willie Quinn, Chief Executive Officer. “BDC-3042 deserves rapid development, especially given its enormous commercial potential. We are launching a process to find a partner with the resources to accelerate development and optimize commercialization.”

BDC-3042 is a proprietary agonist antibody that targets dectin-2, an immune-activating receptor expressed by tumor-associated macrophages (TAMs). Dectin-2 is a C-type lectin receptor best known for its role in pathogen recognition and induction of protective immune responses against fungi and other microbes. This single-agent, dose-escalation Phase 1 clinical study is evaluating BDC-3042 in patients with metastatic or unresectable triple-negative breast cancer (TNBC), clear cell renal cell carcinoma (ccRCC), colorectal cancer (CRC), melanoma, non-small cell lung cancer (NSCLC), and ovarian cancer.

Key Clinical Study Findings:

Seventeen patients with six different tumor types and a median of four prior lines of therapy were enrolled across the seven dose cohorts. As of the April 7, 2025 data cut-off, results showed:

- BDC-3042 was well tolerated up to the highest dose level tested (10 mg/kg q2w), with no dose-limiting toxicities observed. Across all dose cohorts:
  - No grade 4 or 5 drug-related adverse events (AEs) were reported
  - No drug-related serious adverse events (SAEs) were reported
  - No drug-related treatment discontinuations
  - The most frequent drug-related AEs were fatigue (12%), flatulence (12%), and nausea (12%)
- BDC-3042 demonstrated favorable pharmacokinetics (PK) providing ample exposure and flexibility to widen the dosing interval
- Biological activity was confirmed, with evidence of target engagement and peripheral immunostimulatory effects consistent with preclinical studies
  - 100% (5/5) of patient samples had detectable dectin-2 staining when assessed by immunohistochemistry (IHC)
- The study provided evidence of monotherapy anti-tumor activity
  - One NSCLC patient from the 10 mg/kg cohort had an unconfirmed partial response and remains on study beyond 18 weeks
  - 80% of evaluable patients (12/15) had SD or better as their best response
  - Four out of five patients who had progressed after previous treatment with PD-1/PD-L1 blockers had SD with some reduction in tumor size
  - All three NSCLC patients had SD or better with some reduction in tumor size

The dose-escalation data support the selection of 10 mg/kg q2w as a recommended Phase 2 dose (RP2D), alongside potential exploration of other doses and schedules. The results support further clinical development in NSCLC and other post-immunotherapy settings, as patients previously treated with PD-(L)1 inhibitors appear to have more dectin-2 expression and may experience improved outcomes.

“BDC-3042 demonstrated a very favorable safety profile across all seven dose levels in a late-line patient population that is difficult to treat,” said Ecaterina Dumbrava, M.D., associate professor of Investigational Cancer Therapeutics at The University of Texas MD Anderson Cancer Center. “The favorable safety, PK, and immunostimulatory effects of BDC-3042 support its further study in selected indications and underscore its combination potential with immune checkpoint inhibitors and other therapies.”

Details about the poster presentations can be found on the AACR website. Additionally, a copy of each poster is available on the Publications page of the Bolt Biotherapeutics website.

About Bolt Biotherapeutics, Inc.
Bolt Biotherapeutics is a clinical-stage biopharmaceutical company developing novel immunotherapies for the treatment of cancer. Bolt Biotherapeutics’ pipeline candidates are built on the Company’s deep expertise in myeloid biology and cancer drug development. The Company’s pipeline includes BDC-3042, a first-in-class agonist antibody that activates macrophages by targeting dectin-2, and BDC-4182, a next-generation Boltbody™ Immune-Stimulating Antibody Conjugate (ISAC) clinical candidate targeting claudin 18.2. BDC-3042 is currently in a Phase 1 dose-escalation trial that includes patients with any of seven different solid tumor types. BDC-4182 is supported by strong in vitro and in vivo data demonstrating potent anti-tumor activity, and activities are underway to support the initiation of clinical trials in second quarter 2025. Bolt Biotherapeutics is also developing additional Boltbody™ ISACs in strategic collaborations with leading biopharmaceutical companies. For more information, please visit https://www.boltbio.com/.

Forward-Looking Statements
This press release contains forward-looking statements about us and our industry that involve substantial risks and uncertainties and are based on our beliefs and assumptions and on information currently available to us. All statements other than statements of historical facts contained in this press release, including statements regarding the future potential of BDC-3042 in various settings and at various doses, likely development path for BDC-3042, the ability for BDC-3042 to safely combine with other treatments, BDC-3042’s enormous commercial potential, our ability to find a development partner for BDC-3042 and to accelerate the development and optimize commercialization of BDC-3042, and the initiation of future clinical trials, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “on track,” “plan,” “potential,” “predict,” “project,” “should,” “will,” or “would,” or the negative of these words or other similar terms or expressions. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements represent our current beliefs, estimates and assumptions only as of the date of this press release and information contained in this press release should not be relied upon as representing our estimates as of any subsequent date. These statements, and related risks, uncertainties, factors and assumptions, include, but are not limited to: the potential product candidates that we develop may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release; such product candidates may not be beneficial to patients or become commercialized; and our ability to maintain our current collaborations and establish further collaborations. These risks are not exhaustive. Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future. Further information on factors that could cause actual results to differ materially from the results anticipated by our forward-looking statements is included in the reports we have filed or will file with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2024. These filings, when available, are available on the investor relations section of our website at investors.boltbio.com and on the SEC’s website at www.sec.gov.

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