Biomed Valley Discoveries Announces Publication of Results from Phase 1b Study of Pembrolizumab in Combination with Clostridium novyi-NT (CNV-NT/BVD-550) in Patients with Advanced Solid Tumors in Clinical Cancer Research

- Led by researchers at MD Anderson Cancer Center, the study demonstrated an overall objective response rate of 25% (n=4) among patients with various solid tumor types
- BVD is advancing CNV-NT, an attenuated form of the *Clostridium novyi* bacteria delivered via intratumoral injection, as a novel modality to target the necrotic cores of tumors and unleash a powerful tumor-destroying attack
- The Phase 1b study findings demonstrate the potential of CNV-NT and pembrolizumab combination as a promising therapeutic strategy for treatment-refractory solid tumors

KANSAS CITY, Mo., October 7, 2025 – Biomed Valley Discoveries (BVD), a clinical-stage biotechnology company guided by its founders' intent of bringing hope for life to patients, today announced that results from a Phase 1b study investigating the safety and synergistic effects of intratumoral injection of *Clostridium novyi*-NT in combination with pembrolizumab in patients with advanced solid tumors were recently published in *Clinical Cancer Research*, a journal of the American Association for Cancer Research. Conducted in collaboration with researchers at The University of Texas MD Anderson Cancer Center, the Phase 1b study demonstrated an overall objective response rate (ORR) of 25% (n=4) among patients with various advanced solid tumor malignancies. These findings build upon results from an earlier Phase 1 study that demonstrated encouraging safety, tolerability, and anti-tumor results with CNV-NT monotherapy.

BVD is researching *Clostridium novyi*-NT (non-toxic) (CNV-NT/BVD-550) – an attenuated form of the *Clostridium novyi*, or *C. novyi*, bacteria – as a modality to target the necrotic cores of tumors and unleash a powerful tumor-destroying attack. *C. novyi* is a spore-forming, anaerobic bacterium that can only thrive in hypoxic regions (regions that lack oxygen) such as the necrotic core of a tumor. The consequence of germination and growth of CNV-NT results in direct tumor destruction as well as activation of the host immune system.

"A cancer-fighting presence in the necrotic cores of tumors is critical because current standard-of-care therapies typically do not destroy all cancer cells within these regions. This may, in turn, contribute to cancer's growth and progression. CNV-NT can uniquely target and destroy typically difficult-to-access necrotic cores in tumors," said Brent Kreider, Ph.D., President of BVD and a co-author of the publication. "The powerful anti-cancer benefit of bacteria-based therapy was demonstrated well over a century ago. With the publication of these new data, we are excited to reinforce the potential of this approach to address critical unmet needs of cancer patients who may have few other treatment options."

"The innate immune response we observed with CNV-NT in the Phase 1 monotherapy trial suggested that pairing this therapeutic modality with an immunotherapy like pembrolizumab could amplify and enhance the durability of its cancer-fighting attack. The encouraging early data on this combination study support this hypothesis," said Sarina Piha-Paul, M.D., professor, of Investigational Cancer Therapeutics at MD Anderson, and corresponding author of the publication.

Study Design and Results

A total of 16 patients with advanced solid tumors were enrolled in the Phase 1b study. Patients received a single intratumoral injection of *C. novyi*-NT on day 8 across four dose cohorts (3×10^4 to 100×10^4 spores) with pembrolizumab (200 mg intravenously) every 3 weeks, day 0–24 months.

The combination therapy was generally well tolerated, with one grade 3 dose-limiting toxicity of abscess formation. The remainder of treatment-related adverse events, observed in ≥10% of patients, were grade 1 or 2 and included injection site reaction, pyrexia, pruritus, leukopenia, and anemia. The maximum tolerated dose was determined to be 200 mg pembrolizumab every 3 weeks and a single dose of 100×10^4 *C.novyi*-NT spores.

The confirmed ORR of 25% was observed among four patients with various tumor types, including nonkeratinizing undifferentiated nasopharyngeal squamous carcinoma, human papilloma virus–positive squamous cell carcinoma of the base of the tongue, vulvar melanoma, and chordoma (a rare cancer that originates in the bones of the spine or the skull). Among these patient responders, three partial responses and one complete response were observed, with a median duration of response of 10.93 months. Stable disease was observed in 69% of patients.

“With promising therapeutic viability data now in hand for CNV-NT as both a monotherapy and a combination therapy, we are evaluating possible partnerships for the next stage of development,” said Dr. Kreider.

About Biomed Valley Discoveries

Biomed Valley Discoveries (BVD) is a clinical-stage biotechnology company on a quest to make a meaningful difference for patients and their families. Founded by Jim and Virginia Stowers, BVD is exclusively guided by its founders’ intent of bringing hope for life to patients. As part of the Stowers Group of Companies, BVD receives stable and sustainable resources through private institutional funding via American Century Investments, an asset management firm founded by Jim Stowers. Because of this innovative funding model, BVD has created a purposefully reimagined approach to every aspect of business operations and the pursuit of groundbreaking medicines. BVD is currently advancing three novel oncology programs, including: ulixertinib, a highly selective, first in class ERK 1/2 inhibitor; TEM8-directed antibody drug conjugates (ADCs); and clostridium novyi-NT, a cancer-fighting bacteria.

To learn more, visit BVD’s **website** or connect on **LinkedIn**. For partnering and out-licensing opportunities, email BD@biomed-valley.com.

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