



Seven and Eight Biopharma's BDB001 in Combination with an anti-PD-L1 mAb Shows Favorable Safety and Clinical Responses in Interim Phase 1 Data Presented at the 2021 SITC Annual Meeting

November 13, 2021 08:00 AM Eastern Standard Time

EDISON, N.J., – Seven and Eight Biopharmaceuticals Inc., a clinical stage biotechnology company developing proprietary novel immuno-oncology therapies to activate the immune system against cancer, announces the presentation of interim Phase 1 data for BDB001 in combination with atezolizumab in advanced solid tumors at the 2021 Society for Immunotherapy of Cancer (SITC) Annual Meeting.

BDB001 is an immune modulator capable of activating dendritic cells to initiate both innate and adaptive immunity against cancer. BDB001 is a first-in-class TLR7/8 agonist delivered intravenously, allowing for broader treatment of solid tumors. Previously, Seven and Eight Biopharma reported that intravenous administration of BDB001 both as monotherapy and in combination with an anti-PD-1 mAb exhibit favorable tolerability and robust systemic immune activation leading to durable clinical responses in multiple advanced solid tumor types (SITC, 2020¹; ASCO, 2021²).

The presentation at SITC 2021 provides interim safety and efficacy results for a Phase 1 dose escalation / expansion trial of BDB001 in combination with atezolizumab in advanced solid tumors ([NCT04196530](#)). The results show that BDB001 in combination with atezolizumab is well tolerated with evidence of robust immune activation leading to clinical responses in multiple tumor types.

“It is encouraging to see that BDB001 in combination with atezolizumab can be safely delivered intravenously and produces clinical responses in heavily pre-treated tumors” said lead author and study investigator Dr. Manish R. Patel, of Florida Cancer Specialists/Sarah Cannon Research Institute.

“These promising interim results show that BDB001 in combination with atezolizumab represents a novel and viable treatment for advanced solid tumors. It is especially encouraging to see responses in both PD-1 naïve and refractory tumors.” said Dr. Robert H.I. Andtbacka, Chief Medical Officer, Seven and Eight Biopharma. “The Phase 1 trial helped establish the BDB001 phase 2 dose which is being evaluated in an ongoing Phase 2 trial ([NCT03915678](#)) of BDB001 in combination with atezolizumab and radiotherapy in selected tumor types.”

“We are very excited about the clinical data for BDB001 in combination with atezolizumab, as we continue to advance our robust immuno-oncology pipeline in treatments beyond anti-PD-(L)1, including preclinical platform programs in TLR Ligand Antibody Conjugation” said Dr. Walter Lau, Chief Executive Officer, Seven and Eight Biopharma.

Presentation Details:

Abstract Title: BDB001, a Toll-Like Receptor 7 and 8 (TLR7/8) agonist, can be safely administered intravenously in combination with atezolizumab and shows clinical responses in advanced solid tumors.

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Session: Poster Presentation

On-Demand Session Release Date and Time: November 13th, 2021 @ 7:00 AM

Abstract Number: 472

The poster presentation will be available at the [SITC 2021 Annual Meeting](#) website.

Abstract Summary:

- Seven and Eight Biopharma's systemic delivery of the TLR 7 and 8 dual agonist BDB001 is first in class.
- BDB001 was delivered safely intravenously in combination with atezolizumab.
- BDB001 in combination with atezolizumab showed robust dose dependent immune activation without increased risk of cytokine release syndrome.
- Overall, BDB001 was well tolerated and 31.7% of subjects did not have any treatment related adverse events. No DLTs occurred and there were no Grade 4 or 5 Adverse Events.
- Clinical responses were seen in subjects with urothelial carcinoma and non-small cell lung cancer and showed evidence of robust anti-tumor immune activation.
- Clinical responses were seen in tumors that had progressed on anti-PD-1 therapy and with low probability of responding to anti-PD-(L)1 therapy based on their PD-L1 negative, MSI-stable, and Tumor Mutational Burden-low status.
- A Phase 2 trial has been initiated and is actively enrolling subjects to further investigate BDB001 in combination with atezolizumab and radiotherapy in patients with advanced solid tumors
- BDB001 in combination with atezolizumab represents a novel and viable therapeutic option for patients with advanced solid tumors.

About Seven and Eight Biopharma

Seven and Eight Biopharmaceuticals Inc. is an Edison, New Jersey based, clinical stage biotechnology company focused on the development and commercialization of novel immunotherapies for cancer. The company specializes in TLR7/8 programs to treat cancer and has built a comprehensive global intellectual property portfolio in the category of toll-like receptor modulators. Managed by a seasoned team of professionals, the company is progressing a proprietary pipeline of cancer therapeutics in the U.S., with the lead products BDB001 and BDB018 in Phase 1 and 2 clinical trials in monotherapy and in combination with both anti-PD-1 and anti-PD-L1 monoclonal antibodies.

For more information, please visit www.7and8biopharma.com.

References

¹ [J Immunother Cancer 2020;8 \(Suppl 3\) A324](#)

² [J Clin Oncol 39, 2021 \(suppl 15; abstr 2512\)](#)

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