Seven and Eight Biopharma's BDB001 in Combination with Pembrolizumab Shows Favorable Safety and Clinical Responses in Interim Phase 1 Data Presented at the 2021 ASCO Annual Meeting

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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 Phase 1 data for BDB001 in combination with pembrolizumab in advanced solid tumors at the 2021 American Society of Clinical Oncology (ASCO) 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 as monotherapy showed favorable tolerability and robust systemic immune activation leading to durable clinical responses.

The poster discussion session at ASCO for Abstract #2512 revealed new interim safety and efficacy results for a Phase 1 dose escalation / expansion trial of BDB001 in combination with pembrolizumab in advanced solid tumors (NCT03486301). The results show that BDB001 in combination with pembrolizumab was well tolerated, and induced robust immune activation leading to clinical responses. Based on these results, the recommended Phase 2 dose (RP2D) of BDB001 was determined and is currently being further evaluated in an ongoing dose expansion phase.

"It is encouraging to see that BDB001 in combination with pembrolizumab 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 represents a novel and viable treatment for advanced solid tumors. It is especially encouraging to see responses in PD-L1 negative and refractory tumors" said Dr. Robert H.I. Andtbacka, Chief Medical Officer, Seven and Eight Biopharma. "We continue to enroll subjects in the dose expansion part of this trial, to further evaluate safety, efficacy, and immune modulatory effects in the tumor microenvironment."

"We are very excited about the clinical data for BDB001 in combination with pembrolizumab, 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, an intravenously administered toll-like receptor 7 and 8 (TLR7/8) agonist, in combination with pembrolizumab in advanced solid tumors: Phase 1 safety and efficacy results.
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> **Abstract Authors:** Manish R. Patel, Anthony W. Tolcher, Drew W. Rasco, Melissa Lynne Johnson, Angela Tatiana Alistar, Lixin Li, Alexander H. Chung, Robert H.I. Andtbacka
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> **Session Title:** Poster Discussion Session, Developmental Therapeutics—Immunotherapy

On-Demand Session Release Date and Time: 6/4/2021, 9:00 AM-10:00 AM

Abstract Number: 2512

The poster presentation will be available on the ASCO Meeting Library and on the Company's website at https://7and8biopharma.com/events-presentations/

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 pembrolizumab.
- BDB001 in combination with pembrolizumab showed robust dose dependent immune activation without increased risk of CRS, as evidenced by minimal increase in pro-inflammatory/CRS cytokines, IL-6, IL-10, and TNF-α.
- Overall, BDB001 was well tolerated and over 21% of subjects did not have any treatment related adverse events. There were few Grade 3 and no grade 4 or 5 adverse events.
- At BDB001 Levels 3 and 4, 19 subjects were evaluable for efficacy. There was evidence of:
    - Rapid and deep clinical responses were observed in tumors with low response rate to anti-PD-1 therapy based on their PD-L1 negative, MSI-stable, and TMB-low status.
    - 5 clinical responses including 1 Complete Response (CR)
    - Overall Response Rate (ORR) was 26%; Disease Control Rate (DCR) of 58%
    - Clinical responses were seen in subjects with cholangiocarcinoma, hepatocellular carcinoma, melanoma, ovarian carcinoma, and triple negative breast cancer.
    - Robust anti-tumor immune activation via IP-10 (CXCL10) upregulation, which correlated with clinical responses.
- BDB001 in combination with pembrolizumab is a promising novel therapeutic option for patients with advanced solid tumors and is being evaluated in an ongoing dose expansion trial.

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 product BDB001 in Phase 1 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

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