

## **ImmPACT Bio Announces FDA Clearance of IND for Novel Bispecific CAR to Treat Aggressive B-cell Lymphoma**

*Phase 1/2 clinical trial expected to launch in early 2023 and will evaluate safety and preliminary impact on disease activity of IMPT-314*

**WEST HILLS, Calif.**, January 23, 2023 — ImmPACT Bio USA, Inc. (“ImmPACT Bio”), a clinical-stage company developing transformative logic-gate-based chimeric antigen receptor (CAR) T-cell therapies for treating cancer, today announced clearance of its first Investigational New Drug (IND) application by the U.S. Food and Drug Administration (FDA) for IMPT-314, a bispecific “OR-Gate” autologous CAR T-cell therapy targeting the B-cell antigens CD19 and CD20. IMPT-314 will be studied in a Phase 1/2 clinical trial in patients with aggressive B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL).

“This IND clearance is a significant milestone for our company,” said Sumant Ramachandra, M.D., Ph.D., president and chief executive officer of ImmPACT Bio. “Results from an investigator-led study evaluating this CAR T-cell therapy demonstrated that 70 percent of patients achieved a complete response with significant durability of remission. These initial efficacy results combined with the favorable safety profile show that IMPT-314 could potentially be a best-in-class treatment for patients with B-cell lymphomas. We look forward to initiating this Phase 1/2 trial to help cancer patients who need new therapies.”

ImmPACT Bio plans to initiate the Phase 1/2 clinical trial of IMPT-314 in the first quarter of 2023. In January 2022, the Company raised \$111 million in a Series B financing round to build a talented team of cell therapy, oncology, and immunology specialists, as well as its clinical manufacturing and quality control laboratory facility in Los Angeles.

Based on the pioneering work of Yvonne Chen, Ph.D., associate professor at the University of California, Los Angeles (UCLA), this CD19/CD20-directed bispecific CAR has demonstrated clinically meaningful and differentiated results in an ongoing investigator-led study at UCLA. Principal investigator Sarah Larson, M.D., studied patients with non-Hodgkin lymphoma (NHL), including various subtypes of aggressive B-cell lymphoma, DLBCL, non-indolent or refractory follicular lymphoma (FL), and mantle cell lymphoma (MCL). Data from the study demonstrated 90 percent of patients (9/10) had an objective response with 70 percent (7/10) of patients achieving a durable complete response (CR). Of note, no patients had neurotoxicity, also known as immune effector cell-associated neurotoxicity syndrome (ICANS). Patients had Grade 1 or no cytokine release syndrome (CRS). Median follow-up was more than 20 months and median progression-free survival (PFS) is 18.2 months. These results from the first 10 evaluable patients were recently published in [Cancer Discovery](#). The UCLA study continues to enroll additional patients.

“Dr. Chen designed this bispecific CAR to address antigen escape, which is a key challenge for current approved CD19 therapies for hematological malignancies,” said Dr. Larson. “We tested

this anti-CD19/CD20 CAR-T cell therapy in patients with relapsed or refractory NHL and are encouraged about the potential of this therapy for patients.”

In addition to IMPT-314, ImmPACT Bio is investigating two other platform logic-gated CAR technologies targeting solid tumors with preclinical candidates.

### **About Non-Hodgkin Lymphoma**

Non-Hodgkin lymphoma (also known as non-Hodgkin’s lymphoma or NHL) is a type of cancer that forms in the lymphatic system, which is part of the immune system that helps protect the body from infection and disease. In NHL, white blood cells called lymphocytes grow abnormally and can form growths (tumors) throughout the body. There are many subtypes of NHL. Diffuse large B-cell lymphoma and follicular lymphoma are among the most common subtypes. Symptoms include swollen lymph nodes, fever, belly pain, or chest pain. Treatments may include chemotherapy, radiation therapy, stem-cell transplant, or medications.

### **About ImmPACT Bio**

ImmPACT Bio USA, Inc., is a clinical-stage company dedicated to the discovery of transformative chimeric antigen receptor (CAR) T-cell therapies for cancer patients who have exhausted their treatment options. The company’s logic-gate-based CAR T-cell platforms, licensed from UCLA Technology Development Group (TDG), address key biological challenges in treating cancer. ImmPACT Bio’s technologies are specifically designed to prevent antigen escape, and to overcome the immunosuppressive tumor microenvironment. The company’s technology is based on the work of pioneering scientists Yvonne Chen, Ph.D., and Antoni Ribas, M.D., Ph.D., both from University of California, Los Angeles (UCLA). In addition, another logic-gate-based CAR T-cell technology is based on the work of Gideon Gross, Ph.D., from the MIGAL-Galilee Research Institute, to address the prevention of ‘on-target – off-tumor’ toxicities. For more information, visit [www.immpact-bio.com](http://www.immpact-bio.com).

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