ImmunoGenesis Doses First Patient in Phase 1/2 Clinical Trial of IMGS-101 in Combination With Balstilimab (anti-PD-1) and Zalifrelimab (anti-CTLA-4) in Relapsed or Refractory Advanced Prostate, Pancreatic, and HPV(-) Head & Neck Tumors

IMGS-101 is the only known reducer of solid tumor hypoxia, offering the potential to enhance the efficacy of immunotherapy

Houston, Texas, March 6, 2025 – ImmunoGenesis, a clinical-stage biotech company developing innovative, science-driven immunotherapies, today announced the first patient has been dosed in the company's Phase 1/2 clinical trial of its hypoxia reversal agent IMGS-101 (evofosfamide) in combination with Balstilimab (anti-PD-1) and Zalifrelimab (anti-CTLA-4) at The University of Texas MD Anderson Cancer Center in Houston, Texas. Tumor hypoxia (low oxygen levels) is an immunosuppressive factor in solid tumors. By reversing hypoxia, IMGS-101 may improve the efficacy of immunotherapies in cancer types that are otherwise resistant to immune-based treatments.

The Phase 1/2, open-label, multicenter study (NCT06782555) consists of a dose escalation and expansion portion to evaluate the safety, pharmacokinetics, and anti-tumor activity of IMGS-101 in combination with Balstilimab and Zalifrelimab in adult patients with locally advanced or metastatic castration-resistant prostate cancer (CRPC), pancreatic cancer, and human papillomavirus-(HPV) negative squamous cell carcinoma of the head and neck (SCCHN). The study is being conducted in collaboration with Agenus, a clinical-stage immuno-oncology company developing the checkpoint inhibitors Balstilimab and Zalifrelimab.

"Launching this trial represents a significant milestone in our mission to target key mechanisms of immune resistance," said ImmunoGenesis President and CEO James Barlow. "By targeting and reversing hypoxia, we aim to unlock the immune system's full potential and redefine the therapeutic landscape for these cancers with high unmet medical needs."

"This trial marks an exciting step forward in addressing one of the key challenges in cancer immunotherapy," said Dr. Charles Schweizer, Senior Vice President of Clinical Development at ImmunoGenesis. "Hypoxia limits T-cell infiltration and suppresses immune responses, especially in prostate, pancreatic, and head and neck cancers. By reversing hypoxia, IMGS-101 may restore T-cell access to tumors, enhancing the effectiveness of checkpoint inhibitors and potentially transforming outcomes in these hard-to-treat cancers."

About ImmunoGenesis
ImmunoGenesis is a clinical-stage biotech company dedicated to transforming immuno-oncology by targeting key mechanisms of immune resistance. The company's lead product, IMGS-001, is a cytotoxic, dual-specific PD-L1/PD-L2 antibody currently in a phase 1a/b clinical trial for the treatment of immune-excluded ("cold") tumors, which account for more than half of all cancers. In addition to its lead program, the company is developing a number of novel approaches to overcome immune resistance in cold tumors. ImmunoGenesis designs therapies to address the pathology of these tumors, overcoming immune exclusion to elicit a robust immune response. For more information, visit www.immunogenesis.com.

About IMGS-101
IMGS-101, also known as Evofosfamide, is a 2-nitroimidazole prodrug of the cytotoxin bromo-isophosphoramide mustard (Br-IPM) originally developed as a hypoxia-activated prodrug. ImmunoGenesis' Founder, Dr. Michael A. Curran from MD Anderson, demonstrated in his lab that IMGS-101 has the unique ability to address one of the most significant immunosuppressive barriers by reversing hypoxia. In pre-clinical models and a Phase 1 clinical study, IMGS-101 restored T-cell function and

showed early signs of synergizing with checkpoint inhibitors. ImmunoGenesis is developing IMGS-101 as a hypoxia-reversal agent that can condition tumors to respond to checkpoint inhibition.

About Balstilimab
Balstilimab is a novel, fully human monoclonal immunoglobulin G4 (IgG4) designed to block PD-1 (programmed cell death protein 1) from interacting with its ligands PD-L1 and PD-L2. It has been evaluated in >900 patients to date and has demonstrated clinical activity and a favorable tolerability profile in several tumor types. Balstilimab is being developed by Agenus, Inc.

About Zalifrelimab
Zalifrelimab is a novel, fully human monoclonal immunoglobulin G1 (IgG1) designed to block CTLA-4 (cytotoxic T-lymphocyte associated antigen 4) from interacting with its ligands CD80 and CD86. CTLA-4 is a negative regulator of immune activation that is considered a foundational target within the immuno-oncology market. Zalifrelimab is being developed by Agenus, Inc.

Disclosure
Dr. Curran's financial relationship with ImmunoGenesis is managed and monitored by the MD Anderson Conflict of Interest Committee.

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