CaroGen Corporation

FOR IMMEDIATE RELEASE

CaroGen Receives FDA IND Authorization for First-in-Class HBV Immunotherapy

Farmington, CT – June 24, 2026 – CaroGen Corporation, a clinical-stage biotechnology company advancing novel immunotherapies for chronic infectious diseases and cancer, today announced that the U.S. Food and Drug Administration (FDA) has authorized the company to proceed with its first-in-human clinical study under Investigational New Drug (IND) Application No. 31717 for **CARG-201**, a potentially first-in-class therapeutic vaccine aimed at providing a functional cure for chronic Hepatitis B Virus (HBV) infection—a condition affecting more than 254 million people worldwide and representing a $3 billion-plus annual therapy market with no functional cure.

In a letter dated June 23, 2026, the FDA notified CaroGen that all clinical hold issues for IND 31717 had been satisfactorily addressed and that the company may proceed with its planned clinical study. This milestone underscores both the scientific promise of CARG-201 and the strength of CaroGen's AVIDIO™ platform technology, and marks a critical inflection point in the company's mission to deliver the first functional cure for chronic HBV.

Built upon CaroGen's proprietary **AVIDIO™ platform**, CARG-201 leverages engineered, self-replicating mRNA-based virus-like vesicles (VLVs) capable of expressing multiple HBV antigens. Licensed from Yale School of Medicine and co-developed by Dr. John Rose, Professor of Pathology at Yale, and Dr. Michael Robek, now Chair and Professor at Albany Medical College, this approach is designed to break immune tolerance and drive durable antiviral immunity, as demonstrated in compelling preclinical studies.

CARG-201 has demonstrated compelling preclinical superiority in head-to-head comparisons against the leading benchmark HBV immunotherapy in clinical development. In a high viral antigen load setting—the most clinically challenging patient population—CARG-201 achieved approximately a one-log reduction in serum HBV surface antigen (HBsAg), while the comparator arenavirus vector-based program (GS-2829/GS-6779, developed by HOOKIPA in collaboration with Gilead Sciences) showed no effect in the same high viral load group. This distinction is critical: high viral antigen load patients represent the largest and most difficult-to-treat segment of the chronic HBV population, and no existing therapeutic has demonstrated the ability to overcome this immune tolerance barrier. CARG-201's intrinsic adjuvant mechanism—driven by dsRNA intermediates that induce endogenous interferon-α/β without requiring exogenous adjuvants—is believed to underlie this differentiated efficacy profile (Yarovinsky et al., iScience, 2019; Schmidt et al., J Infect Dis, 2024).

“Despite the failure of many large and small biotech and pharmaceutical companies to develop a curative immunotherapy for HBV, our team at CaroGen stayed the course,” said **Dr. Bijan Almassian**, Co-Founder and Chairman of the Board of Directors of CaroGen Corporation. “We persevered with minimal resources and often without salaries, driven by science and by a mission far greater than individual ambition. Today, we are one step closer to delivering a functional cure for HBV patients.”

Since its founding in 2012 as a Yale spin-off, CaroGen has received approximately $11.3 million in peer-reviewed, non-dilutive federal funding from the National Institutes of Health (NIH) and the U.S. Department of Defense (DoD). This federal support—contrasting with the lack of early local venture capital backing—has been critical to advancing CARG-201 through all pre-clinical milestones and to the clinic.

About CaroGen Corporation
CaroGen Corporation is a Connecticut-based biotechnology company pioneering a next-generation class of immunotherapies using its patented **AVIDIO™ platform**, originally developed at Yale School of Medicine. Its pipeline includes CARG-201 for chronic hepatitis B, CARG-2020 for solid tumors, and a universal influenza vaccine. CaroGen holds a robust intellectual property portfolio, including a composition-of-matter patent through 2044, and is supported by approximately $11.3 million in non-dilutive funding from NIH and DoD.

To learn more, visit www.carogencorp.com

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