CaroGen Corporation
Creating a Wave of Transformative Immunotherapies...

June 18, 2018
CaroGen Corporation
Farmington, CT

CaroGen announces: (i) clinical candidate selection for treatment of chronic hepatitis B virus, (ii) a successful pre-IND interaction with the FDA, (iii) issuance of a US patent, and (iv) award of an SBIR grant.

CaroGen, a developer of transformative immunotherapies for infectious disease and cancer, having its initial focus on development of a cure for patients with chronic hepatitis B (CHB), announced that the Company has selected a candidate for advancement into clinical studies. The candidate Virus-Like Vesicle (VLV), known as CARG-101, has many attributes that make it attractive for advancement including expression of three major antigens from Hepatitis B Virus (HBV) and its ability to reduce serum HBsAg to undetectable levels in up to 40% of mice in an animal model of CHB. "*We anticipate an IND and start of phase I in the first half of 2019*", remarked Dr. Bijan Almassian, President and CEO of CaroGen Corporation. He went on to further indicate that "*this candidate represents several years of refinement of the VLV platform, which also can be applied as therapy or prevention to other infectious diseases or oncological indications*".

To advance CARG-101 into clinical trials, CaroGen has interacted with the FDA by assembling a pre-IND package last fall. This package was submitted in October 2017 and the responses from the FDA were received in November. "*By all accounts, the responses were very positive and our interaction through the pre-IND process has made us very confident in advancing our clinical candidate, CARG-101, further*," said Dr. Valerian Nakaar, Vice President of R&D at CaroGen.

CaroGen also announced that on June 5th, 2018, the USPTO issued US patent 9,987,353 to Yale University for "*Virus-Like Vesicles (VLVs) Based Vaccines to Prevent or Treat Chronic Hepatitis B (HBV) Infection*." The inventors on the patent are Dr. Michael Robek, an expert on HBV and Professor of Immunology & Microbial Diseases at Albany Medical

College; Dr. John Rose, an eminent virologist and Professor of Pathology and Director in the Virology and Vaccine Development Program at Yale University School of Medicine, and Dr. Tracy Reynolds, then a graduate student at Yale University. CaroGen holds an exclusive license to this IP from Yale University. "*We are very proud to make this announcement as it adds great value to CaroGen's patent portfolio and validates our claims to utilize our platform for treatment of chronic Hep B*," said Dr. Almassian.

Lastly, CaroGen announced today that a Small Business Innovation Research (SBIR) Program grant was awarded for "*Enhancing Immunogenicity of VLV-Based Vaccines for Treatment of Chronic HBV*". This Phase I grant award from the National Institute for Diabetes and Digestive and Kidney Diseases (NIDDK) for approximately $225,000 is for a term of 1 year. Dr. Nakaar, the Principal Investigator on the grant stated, *"We are extremely pleased with this award because it provides validation for our platform technology. In addition, the funds will allow CaroGen to further optimize our HBV VLV for maximal immunogenicity and efficacy as we develop a second generation of our HBV immunotherapy*."

About CaroGen:

CaroGen is creating a wave of transformative immunotherapies for infectious diseases and cancer using its novel VLV platform technology with an initial focus on developing a cure for chronic hepatitis B virus (HBV) infection. The VLV technology, developed at Yale University School of Medicine, is safe and capable of delivering large payloads for expression of multiple proteins and shRNA. In collaboration with Yale scientists we have established a proof-of concept in animal models with our trivalent HBV clinical candidate and plan to file an IND by the middle of 2019. CaroGen is also exploiting its VLV platform technology to create novel immunotherapies for colorectal cancer in collaboration with scientists from University of Connecticut Health Center.

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