Checkmate Pharmaceuticals Announces Dosing of First Patient in Immuno-Oncology Phase 1b Trial with CMP-001, a TLR9 Agonist

CAMBRIDGE, Mass., April 20, 2016 – Checkmate Pharmaceuticals, a clinical-stage biopharmaceutical company focused on developing novel approaches for cancer immunotherapy, announced today the appointment of David Mauro, M.D., Ph.D. to the newly created position of Chief Medical Officer. Checkmate also announced the dosing of the first patient in a Phase 1b trial with CMP-001 in combination with pembrolizumab in melanoma patients who have either progressed on or failed to respond to at least 12 weeks of anti-PD1 therapy.

CMP-001 is a first-in-class CpG-A oligonucleotide that activates the innate immune system via Toll-like receptor 9 (TLR9). The combination therapy has the potential to increase the proportion of cancer patients who respond to checkpoint inhibitor therapies and to increase the magnitude and duration of the anti-tumor responses, providing added clinical benefit.

Industry Veteran with Immuno-Oncology Clinical Development and Leadership Expertise

Dr. Mauro brings to Checkmate more than 15 years of experience in early and late stage oncology drug development, clinical and translational research, and medical affairs. Previously he served as Executive Vice President and Chief Medical Officer at Advaxis, where he was responsible for the strategy and oversight of the company’s clinical programs, including several combination drug programs with checkpoint inhibitors.

“We welcome David to the Checkmate team at this pivotal time,” said Art Krieg, M.D., Chief Executive Officer of Checkmate. “His deep knowledge and experience in immuno-oncology, and specifically in the development of checkpoint inhibitor combinations, will be invaluable to Checkmate in the clinical development of CMP-001 for patients with advanced cancer.”

Dr. Mauro has held senior level positions at Merck & Co. and Bristol Myers Squibb Company, where he was involved in the clinical development, translational science, and life cycle management for multiple programs, including Keytruda® (pembrolizumab), Erbitux® (cetuximab), Sprycel® (dasatinib), and Sylatron® (peginterferon alfa-2b). He received his Bachelor of Science in Biochemistry from Cornell University, his medical degree and his doctorate in pharmacology from Temple University School of Medicine, and completed his residency training at the National Cancer Institute. As Chief Medical Officer at Checkmate, Dr. Mauro will oversee the development of the Company’s current and future clinical programs, based on the TLR9 mechanism of immune activation.

“I am excited to be joining Checkmate as it progresses CMP-001 into the clinic initially in melanoma patients,” said Dr. Mauro. “I look forward to working with the team to further expand the development of this compound in other indications and checkpoint inhibitor combinations. The immuno-oncology field is evolving rapidly, and I believe that CMP-001 has the potential to increase the response rates to current checkpoint therapies and have a broad impact in the development of new standards of care for oncology treatment.”

Initiation of Phase 1b Trial in Advanced Melanoma with a TLR9 Immune Activator

Checkmate has dosed the first patient in its Phase 1b clinical study of CMP-001. The trial is designed as a multi-center, open-label study of CMP-001 in combination with pembrolizumab for patients with...
advanced melanoma who have either progressed on an anti-PD1, or have failed to respond to at least 12 weeks of therapy. Patients will continue on the approved dose and schedule of pembrolizumab, with the addition of intratumoral CMP-001 therapy. The trial will include a dose escalation study and will enroll patients in an expansion phase, as well as undertake correlative studies to characterize the immune effects of treatment in the blood and tumor. Patients will be monitored for safety and tolerability as well as possible clinical response.

“We are excited to begin our clinical development of this new approach of altering the tumor microenvironment with intratumoral CMP-001,” said Dr. Krieg. “We believe this treatment should convert “cold” tumors, which lack immune activation and are not likely to respond to checkpoint inhibitors, into immunologically “hot” tumors which are much more likely to respond to checkpoint inhibition. This has the potential to induce a powerful anti-tumor CD8+ T cell immune response resulting in significantly increased response rates to checkpoint inhibitor therapy in multiple cancer indications.”

About CMP-001

CMP-001 comprises a CpG-A oligonucleotide packaged within a virus-like particle. It is designed to activate the innate immune system via Toll-like receptor 9 (TLR9) and mediate tumor control by the subsequent induction of both innate and adaptive anti-tumor immune responses. CMP-001 is the only CpG-A oligonucleotide in clinical development. It differs from the other major classes of TLR9 agonists in development, CpG-B, and CpG-C, by its induction of much higher levels of type I interferons, without inducing immune suppressive IL-10. In addition, the virus-like particle nature of CMP-001 will promote formation of immune complexes within tumors, providing an additional mechanism driving anti-tumor immunity. In preclinical models, CMP-001 shows single agent activity in controlling growth of both local and distant tumors, with increased anti-tumor activity seen in combination with systemic anti-PD-1 therapy. CMP-001 was licensed from Kuros Biosciences AG and was formerly known as CYT003. It has previously demonstrated a good safety profile and evidence of immune activity in over 700 patients who participated in clinical trials for non-oncology indications.

About Checkmate

Checkmate Pharmaceuticals is a clinical stage company pursuing a novel approach to specifically activating the innate arm of the immune system to recognize and ultimately destroy tumor cells. The company is leveraging its expertise and the vast body of knowledge in the field of CpG oligonucleotides and is validating an approach that will combine the ability of CpG DNA to activate an anti-tumor T cell response with checkpoint inhibition to overcome a tumor’s ability to mute the immune response.

Checkmate’s founder and CEO, Dr. Art Krieg, discovered immune stimulatory CpG DNA in 1994. Since then, CpG containing DNA therapies have been administered to thousands of patients showing potent immune activation and an acceptable safety profile. Checkmate is a privately held company headquartered in Cambridge, MA, whose Series A investors include Sofinnova Ventures and venBio. Information regarding Checkmate is available at www.checkmatepharma.com.

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CONTACTS:

Company Contact:
Checkmate Pharmaceuticals, Inc.
Art Krieg, MD, CEO
akrieg@checkmatepharma.com

Media Contact:
MacDougall Biomedical Communications
Karen Sharma
781-235-3060
ksharma@macbiocom.com