Compugen Announces Phase 1/2 Triple Combination Study to Evaluate COM701 in Combination with Bristol-Myers Squibb’s Opdivo® (Nivolumab) and TIGIT Inhibitor

Triple combination study intended to evaluate Compugen’s PVRIG pathway discovery and DNAM axis hypothesis in patients with advanced solid tumors

Study expected to commence in the second half of 2020

Company will host conference call today at 8:30 AM ET

HOLON, Israel – February 20, 2020 – Compugen Ltd. (Nasdaq: CGEN), a clinical-stage cancer immunotherapy company and leader in predictive target discovery, today announced its plan to initiate a Phase 1/2 study evaluating a triple combination of Compugen’s COM701, an investigational anti-PVRIG antibody, in combination with Bristol-Myers Squibb’s PD-1 immune checkpoint inhibitor Opdivo® (nivolumab) and BMS-986207, Bristol-Myers Squibb’s investigational anti-TIGIT antibody.

The triple combination study is designed to evaluate the blockade of the three immune checkpoint pathways – PVRIG, TIGIT and PD-1, and will accelerate the clinical evaluation of Compugen’s science-driven DNAM axis hypothesis in various advanced solid tumors. The study is expected to commence in the second half of 2020, following the clearance of a new Investigational New Drug Application by the U.S. Food and Drug Administration. Compugen will be the study sponsor with Opdivo® and BMS-986207 supplied by Bristol-Myers Squibb.

“We are excited to expand our collaboration with Bristol-Myers Squib with this biomarker-informed triple combination study to accelerate the clinical evaluation of COM701,” said Anat Cohen-Dayag, Ph.D., President and CEO of Compugen. “The triple combination regimen allows us to ultimately test our science-driven hypothesis that the dual inhibition of the DNAM axis with PVRIG and TIGIT blockers, together with the inhibition of the PD-1 pathway, will enable robust activation of T cells leading to anti-
tumor immune responses in cancer patients who are non-responsive or refractory to PD-1 blockers.”

“The initial encouraging signals of anti-tumor activity observed in heavily pretreated patients in the monotherapy dose escalation arm of our ongoing Phase 1 study, paired with our strong scientific rationale and preclinical data, support to our decision to evaluate whether the combination of these three immune checkpoint inhibitors improve patient outcomes and broaden the patient population that will respond to immunotherapies,” added Dr. Cohen-Dayag.

Under the existing collaboration with Bristol-Myers Squibb, COM701 is being investigated as a monotherapy and in combination with Opdivo® in an ongoing Phase 1 study. Following the Companies’ joint decision to move forward with a triple combination study, Compugen will complete the dose escalation arm of the dual combination of COM701 with Opdivo® under its ongoing Phase 1 study. Future studies evaluating COM701 in combination with a PD-1 inhibitor in specific tumor types will be assessed at a later date. As previously indicated, Compugen plans to present initial data from the combination dose escalation study of COM701 with Opdivo® in the second half of 2020. Compugen will continue to advance the biomarker informed monotherapy expansion arm of the ongoing COM701 Phase 1 study, as planned.

The planned open-label Phase 1/2 trial is designed to evaluate the safety, tolerability and antitumor activity of COM701 in combination with Opdivo® and BMS-986207. The study will evaluate a safe and tolerable dose of the combination during dose escalation and antitumor activity in selected tumor types in the expansion cohorts (ovarian cancer, endometrial cancer and a biomarker-driven arm of tumor types with high expression of PVRL2). Dose levels for Opdivo® and BMS-986207 combinations have already been determined through prior testing by Bristol-Myers Squibb, allowing for dose escalation of COM701 with fixed doses of Opdivo® and BMS-986207.

**About COM701**

COM701 is a humanized antibody that binds with high affinity to PVRIG, a novel immune checkpoint discovered computationally by Compugen, blocking the interaction with its ligand, PVRL2. Blockade of PVRIG by COM701 has demonstrated potent, reproducible enhancement of T cell activation, consistent with the desired mechanism of action of activating T cells in the tumor microenvironment to generate anti-tumor immune responses. PVRIG and TIGIT, also discovered by Compugen’s computational discovery platform in 2009, constitute parallel immune checkpoint pathways that counteract DNAM, a costimulatory molecule on T cells and NK cells. As such, preclinical data suggest that the inhibition of PVRIG together with TIGIT and/or PD-1
has the potential to further enhance anti-tumor immune response and improve patient outcomes in a broad variety of tumor types.

COM701 is being evaluated as a monotherapy and in combination with Opdivo® (nivolumab), Bristol-Myers Squibb’s PD-1 inhibitor in a Phase 1 open-label clinical trial in patients with advanced solid tumors. Primary end points of the trial are safety and tolerability; secondary endpoints include preliminary anti-tumor activity, pharmacokinetics and pharmacodynamics in patients with selected tumor types. Data from the monotherapy dose escalation study (n=13) presented at SITC 2019 showed that COM701 is well-tolerated and demonstrated preliminary signs of anti-tumor activity in heavily pretreated patient population Additional information is available at www.clinicaltrials.gov (NCT03667716).

Conference Call and Webcast Information
Compugen management will hold a conference call today, February 20, 2020, at 8:30 AM ET. To access the conference call by telephone, please dial 1-888-407-2553 from the United States, or +972-3-918-0610 internationally. The call will also be available via live webcast through Compugen’s website, located at the following link. Following the live audio webcast, a replay will be available on the Company’s website.

About Compugen
Compugen is a clinical-stage therapeutic discovery and development company utilizing its broadly applicable, predictive computational discovery platforms to identify novel drug targets and develop therapeutics in the field of cancer immunotherapy. The Company’s lead product candidate, COM701, a first-in-class anti-PVRIG antibody, for the treatment of solid tumors, is undergoing a Phase 1 clinical study. In addition, COM902, Compugen’s antibody targeting TIGIT, is expected to enter the clinic in early 2020. The Company's therapeutic pipeline also includes early-stage immuno-oncology programs focused largely on myeloid targets. Compugen’s business model is to selectively enter into collaborations for its novel targets and related drug product candidates at various stages of research and development. The Company is headquartered in Israel, with offices in South San Francisco, CA. Compugen’s shares are listed on the Nasdaq and the Tel Aviv Stock Exchange under the ticker symbol CGEN. For additional information, please visit Compugen’s corporate website at www.cgen.com.

Opdivo® is a registered trademark of Bristol-Myers Squibb Company.
Forward Looking Statement
This press release contains “forward-looking statements” within the meaning of the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, and the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on the current beliefs, expectations and assumptions of Compugen. Forward-looking statements can be identified by the use of terminology such as “will,” “may,” “expects,” “anticipates,” “believes,” “potential,” “plan,” “goal,” “estimate,” “likely,” “should,” “confident,” and “intends,” and similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements include, but are not limited to, statements regarding Compugen’s expected schedule to commence the triple combination study, Compugen’s expected schedule to present initial data from the combination dose escalation study of COM701 with Opdivo®, Compugen’s continuing to advance the monotherapy expansion arm of the ongoing COM701 Phase 1 study and the companies’ planned cohorts for the open-label Phase 1/2 trial. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of Compugen to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Among these risks: Compugen may encounter substantial delays or even an inability to begin clinical trials for any specific product, or may not be able to conduct or complete its trials on the timelines expected and Compugen’s ability to present data derived from collaborations with its partners is dependent in some cases on the agreement of our partners to present such data, and Compugen’s business model is substantially dependent on entering into collaboration agreements with third parties. These risks and other risks are more fully described in the “Risk Factors” section of Compugen’s most recent Annual Report on Form 20-F filed with the Securities and Exchange Commission (SEC) as well as other documents that may be subsequently filed by Compugen from time to time with the SEC. In addition, any forward-looking statements represent Compugen’s views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. Compugen does not assume any obligation to update any forward-looking statements unless required by law.
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