



**FOR IMMEDIATE RELEASE**

**Compugen Announces FDA Clearance of IND Application for Phase 1/2 Triple Combination Study of COM701 with Bristol Myers Squibb's *Opdivo*® (Nivolumab) and TIGIT Inhibitor**

*Study to evaluate simultaneous blockade of PVRIG, TIGIT and PD-1 immune checkpoints*

*Study to accelerate clinical evaluation of Compugen's DNAM axis hypothesis and biomarker-driven approach in advanced solid tumors to broaden patient population responsive to cancer immunotherapy*

*On-track to begin triple combination study during second half of 2020*

HOLON, ISRAEL – June 1, 2020 – [Compugen Ltd.](#) (Nasdaq: CGEN), a clinical-stage cancer immunotherapy company and a leader in predictive target discovery, today announced that the U.S. Food and Drug Administration has cleared the investigational new drug (IND) application for its Phase 1/2 study evaluating the triple combination of COM701, Compugen's first-in-class anti-PVRIG antibody, *Opdivo*® (nivolumab), Bristol Myers Squibb's PD-1 immune checkpoint inhibitor and BMS-986207, Bristol Myers Squibb's investigational anti-TIGIT antibody, in patients with advanced solid tumors.

The triple combination study is designed to evaluate the simultaneous blockade of three immune checkpoint pathways, PVRIG, TIGIT and PD-1, and will accelerate the clinical evaluation of Compugen's DNAM axis hypothesis and biomarker-driven approach in patients with advanced solid tumors, including those that may be refractory or non-responsive to standard-of-care immune checkpoint inhibitors. The study is expected to commence in the second half of 2020.

“This study complements our clinical strategy designed to evaluate the blockade of PVRIG as a monotherapy and in combination with intersecting DNAM axis components

to fully elucidate the role of this potentially foundational axis for cancer immunotherapy,” said Anat Cohen-Dayag, Ph.D., President and CEO of Compugen. “The encouraging clinical data from the ongoing COM701 Phase 1 study evaluating our discovered target PVRIG, and the emerging clinical validation of the TIGIT pathway, leave us increasingly enthusiastic about our science-driven clinical approach evaluating these two complementary yet distinct pathways in combination with PD-1. Importantly, as the only company with wholly-owned clinical candidates against both PVRIG and TIGIT, we are uniquely positioned to address the role of the DNAM axis.”

Henry Adewoye, M.D., Senior Vice President and Chief Medical Officer of Compugen, added, “This study evaluating COM701 in combination with BMS-986207 and nivolumab fits our overall clinical development strategy of advancing novel therapies in cancers with high unmet medical need. We have previously reported partial responses with COM701 as monotherapy and in combination with nivolumab in patients with extremely challenging to treat cancer types, such as MSS platinum resistant primary peritoneal cancer and MSS-CRC. These preliminary clinical data support our preclinical work indicating that PVRIG and PD-1 are distinct pathways and that inhibition of the two may result in clinical benefit to patients. The triple combination will further test our science-driven hypothesis that PVRIG, TIGIT, and PD-1 are non-redundant inhibitory pathways and that their simultaneous blockade is expected to further enhance anti-tumor immune responses and broaden the patient population responsive to cancer immunotherapies. We look forward to collaborating with Bristol Myers Squibb on this important study.”

Under this IND, the Company intends to initiate an open-label Phase 1/2 trial designed to evaluate the safety, tolerability and preliminary antitumor activity of COM701 in combination with *Opdivo*® and BMS-986207 during dose escalation, as well as anti-tumor activity in selected tumor types in the expansion cohorts. 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, and blocks the interaction with its ligand, PVRL2. TIGIT, an immune checkpoint discovered computationally by Compugen in 2009, and PVRIG constitute parallel immune checkpoint pathways that counteract DNAM, a costimulatory receptor on T cells and NK cells. Preclinical data suggest that the blockade of PVRIG induces a robust anti-tumor immune response and

demonstrates synergistic activity when used in combination with inhibitors of TIGIT and/or PD-1. Currently, COM701 is being evaluated in a Phase 1 clinical study. Data from the ongoing study have shown that COM701 is well-tolerated and demonstrated preliminary signals of anti-tumor activity in a heavily pretreated patient population.

### **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 in a Phase 1 clinical study. 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](http://www.cgen.com).

### **Forward-Looking Statement**

This press release contains "forward-looking statements" within the meaning of the Securities Act of 1933 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 the expected timeline to begin the triple combination study during the second half of 2020, Compugen's intention to initiate an open-label Phase 1/2 trial designed to evaluate the safety, tolerability and preliminary antitumor activity of COM701 in combination with *Opdivo*® and BMS-986207 during dose escalation, as well as anti-tumor activity in selected tumor types in the expansion cohorts. 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’s operations could be affected by the outbreak and spread of COVID-19, clinical development involves a lengthy and expensive process, with an uncertain outcome and 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 it expects; Compugen relies, and expects to continue to rely, on third parties to conduct its clinical trials and if these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines (including as a result of the effect of the COVID-19), Compugen may experience significant delays in the conduct of its clinical trials; Compugen’s approach to the discovery of therapeutic products is based on its proprietary computational target discovery infrastructure, which is unproven clinically; Compugen does not know whether it will be able to discover and develop additional potential product candidates or products of commercial value; Compugen’s business model is substantially dependent on entering into collaboration agreements with third parties; and Compugen may not be successful in generating adequate revenues or commercializing aspects of its business model. These risks and other risks are more fully discussed in the “Risk Factors” section of Compugen’s most recent Annual Report on Form 20-F as 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.

**Company contact:**

Elana Holzman

Director, Investor Relations and Corporate Communications

Compugen Ltd.

Email: [elanah@cgen.com](mailto:elanah@cgen.com)

Tel: +972 (3) 765-8124

**Investor Relations contact:**

Bob Yedid

LifeSci Advisors, LLC

Email: [bob@lifesciadvisors.com](mailto:bob@lifesciadvisors.com)

Tel: +1 (646) 597-6989

**Media contact:**

Josephine Belluardo, Ph.D.

LifeSci Communications

Email: [jo@lifescicomms.com](mailto:jo@lifescicomms.com)

Tel: +1 (646) 751-4361