



**FOR IMMEDIATE RELEASE**

**Compugen Announces FDA Clearance of IND Application for  
COM701, a First-in-Class Immuno-Oncology Therapeutic Antibody**

*A Phase 1 trial in patients with advanced solid tumors is to be conducted at multiple  
centers in the United States*

HOLON, ISRAEL – July 2, 2018 – [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 (FDA) has removed the clinical hold on its investigational new drug (IND) application for COM701, a first-in-class immuno-oncology therapeutic antibody targeting PVRIG in patients with advanced solid tumors, and informed the Company it may initiate the clinical study.

“Today is a significant milestone for Compugen, having received clearance from the FDA to advance our lead immuno-oncology program into the clinic. COM701 is a first-in-class drug opportunity that was developed by Compugen from discovery of the drug target by computer prediction through preclinical development, to IND clearance,” stated Anat Cohen-Dayag, PhD, President and CEO of Compugen. “We believe the COM701 preclinical data suggest that targeting PVRIG may effectively stimulate an anti-tumor immune response in certain cancers such as breast, endometrial, ovarian and lung, and specifically in patient populations that are unresponsive to current checkpoint inhibitors.”

“The PVRIG pathway, a new pathway on which we have shed light, is part of a larger complex immuno-oncology biological axis involving the TIGIT and PD-1 pathways. By targeting this pathway, our COM701 program clearly presents a differentiated profile from other drug targets and combination options in the clinic. We are confident we are the only company with an anti-PVRIG candidate available for clinical testing, either as a single agent and in combination with a PD-1 and TIGIT inhibitors, and we are excited to initiate patient dosing with COM701 in a multicenter Phase 1 trial, early in the fall,” Dr. Cohen-Dayag added.

“We worked closely with the FDA in connection with this IND application and are eager to evaluate COM701 in a clinical setting,” said Henry Adewoye, MD, Chief Medical

Officer of Compugen. “We received positive feedback from leading clinical investigators in the field of immuno-oncology who share our excitement for the potential role of the PVRIG pathway in immuno-oncology and our overall clinical program and strategy. We look forward to collaborating with them on this trial.”

Under this IND, the Company intends to initiate a first-in-human Phase 1 study in patients with advanced solid tumors and for whom standard of care therapies are currently ineffective. The clinical trial is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of COM701 as monotherapy and in combination with a PD-1 inhibitor. The Phase 1 trial is planned to be conducted at multiple centers in the United States and site initiation activities are currently underway.

### **About COM701**

COM701 is a humanized hybridoma antibody that binds with high affinity to PVRIG, a novel B7/CD28-like immune checkpoint target candidate discovered by Compugen, blocking its 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. In addition, COM701 combined with antagonist anti-PD-1 antibodies has demonstrated synergistic effects on human T cell stimulation, indicating the potential of these combinations to further enhance immune response against tumors.

Preclinical data for COM701 suggest that PVRIG may be a dominant checkpoint in diverse patient populations with tumors that express elevated PVRL2 as compared to expression of the TIGIT ligand PVR. This include patients with breast, endometrial, and ovarian cancers. In addition, expression studies show that PVRIG and TIGIT, and their respective ligands, are expressed in a broad variety of tumor types, such as those noted above, as well as lung, kidney, and head & neck cancers. In these tumors the blockade of both TIGIT and PVRIG may be required to sufficiently stimulate an anti-tumor immune response, with or without additional PD-1 pathway blockade.

### **About Compugen**

Compugen is a therapeutic discovery and development company utilizing its broadly applicable predictive discovery infrastructure to identify novel drug targets and develop first-in-class therapeutics in the field of cancer immunotherapy. The Company’s therapeutic pipeline consists of immuno-oncology programs against novel drug targets it has discovered, including T cell immune checkpoints and myeloid target programs. 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 R&D facilities in both Israel and South San Francisco, CA. Compugen's ordinary shares are listed on 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 Private Securities Litigation Reform Act of 1995. 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 describe opinions about possible future events. 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 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. Moreover, the development and commercialization of therapeutic candidates involve many inherent risks, including failure to progress to clinical trials or, if they progress to or enter clinical trials, failure to receive regulatory approval. These and other factors, including the ability to finance the Company, 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.

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