



**FOR IMMEDIATE RELEASE**

## **Compugen Presents Initial Clinical Data from Ongoing Phase 1 Trial of COM701 in Patients with Advanced Solid Tumors at SITC 2019**

*COM701 was well-tolerated with no dose-limiting toxicities observed*

*Initial signals of anti-tumor activity observed in heavily pretreated patient population in the dose escalation arm of the study*

HOLON, ISRAEL – November 5, 2019 – [Compugen Ltd.](#) (Nasdaq: CGEN), a clinical-stage cancer immunotherapy company and a leader in predictive target discovery, today disclosed preliminary results from its ongoing Phase 1 dose escalation study of COM701, a first-in-class anti-PVRIG antibody, in patients with advanced solid tumors. COM701 was well-tolerated with no dose-limiting toxicities observed. Furthermore, COM701 demonstrated initial signals of anti-tumor activity in the heavily pretreated patient population enrolled on the study. The clinical data will be presented in a poster titled “Phase 1 Study of the Safety, Tolerability and Preliminary Anti-Tumor Activity of COM701 Monotherapy in Patients with Advanced Solid Tumors” at the 34<sup>th</sup> Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2019) on Friday, November 8, 2019.

“We are encouraged by the emerging safety profile and initial signals of anti-tumor activity of COM701. While the primary objective of this portion of the trial was to test the safety and tolerability of COM701, we were excited to observe early signals of anti-tumor activity in the all-comer, extensively pretreated patient population enrolled, including patients with microsatellite stable colorectal cancer (MSS-CRC), which we may choose to further evaluate in future studies,” said Anat Cohen-Dayag, Ph.D., President and CEO of Compugen. “We believe COM701 has the potential to broaden the checkpoint inhibitor landscape with a biology driven prioritization rationale that addresses indications most relevant to the PVRIG pathway. We look forward to initiating our biomarker driven COM701 monotherapy expansion cohorts in these four prioritized indications – ovarian, endometrial, breast and lung cancers.”

Ecaterina Ileana Dumbrava, M.D., Assistant Professor, Department of Investigational Cancer Therapeutics, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center and presenting author, said “Expanding the reach of cancer immunotherapy drugs to broader patient populations is an urgent need given the number of patients with advanced cancer who are non-responsive or refractory to currently available therapies. The initial signals of anti-tumor activity of COM701 are encouraging, particularly given the heavily pretreated all-comer patient population, with the majority of patients refractory to previous therapy. We observed a trend in dose-response relationship in this hard-to-treat patient population and furthermore, encouraging signals of anti-tumor activity in five out of six treated patients with MSS colorectal, a challenging indication, typically not responsive to current immune checkpoint blockers.”

The reported data are from the monotherapy arm of the ongoing, Phase 1, open-label, dose escalation study and include the first seven (7) cohorts (n=13) at dose levels of 0.01, 0.03, 0.1, 0.3, 1, 3, and 10 mg/kg IV every three (3) weeks.

Key findings presented at the poster in SITC include data updated as of October 15, 2019:

- COM701 was well-tolerated through 10 mg/kg with no dose-limiting toxicities observed.
- The best timepoint response of stable disease (SD)/disease control rate reported in 9 of 13 patients (69%) with a median of seven prior anticancer therapies (range of 2-15).
- All the patients with CRC (N=6) had microsatellite stable status, and 5 of 6 patients (83%) had best timepoint response of stable disease.
- Pharmacokinetic profile supports IV Q3 weekly dosing.
- Peripheral PVRIG receptor occupancy greater than or equal to 90% was demonstrated at COM701  $\geq 1$  mg/kg.
- There are two patients remaining on study treatment with COM701 monotherapy.

Enrollment to COM701 monotherapy dose at 20 mg/kg Q4 weekly is on-going.

The poster will be available on Compugen’s [website](#) following the poster presentation.

### **About the COM701 Phase 1 Study**

The Phase 1 open-label clinical trial of COM701 (anti-PVRIG antibody) is designed to assess the safety and tolerability of administering escalating doses of COM701 monotherapy as well as of combination administration with Bristol-Myers Squibb’s Opdivo® (nivolumab) in patients with advanced solid tumors. Additionally, secondary endpoints include preliminary anti-tumor activity, pharmacokinetics and pharmacodynamics of COM701 monotherapy as well as COM701 in combination with

Opdivo in patients with selected tumor types, including non-small cell lung cancer, ovarian cancer, breast cancer and endometrial cancer. The Phase 1 study, which is expected to enroll approximately 140 patients, is currently recruiting in the United States. Additional information is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT03667716).

### **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 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 computationally, including T cell immune checkpoints and additional early-stage immune-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 facilities in South San Francisco, CA. Compugen's 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," "predicts," "projects," "continues," "targets," "expects," "anticipates," "believes," "potential," "plan," "goal," "estimate," "likely," "should," "could," "would," "confident," "intends" and similar expressions 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 safety and tolerability of COM701, the signal of anti-tumor activity observed in COM701, future clinical trials of COM701 and plans for development of COM701 or any of Compugen's other product candidates or programs. 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 advance through clinical development or receive

regulatory approval; the risk that trials and studies may not have satisfactory outcomes; potential adverse effects arising from the testing or use of COM701 or other product candidates, the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical studies or clinical trials will not be replicated or will not continue in ongoing or future studies or trials involving Compugen's product candidates. 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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