



NEWS RELEASE

Compugen Announces Data Update from COM701 Phase 1 Clinical Trial

2/25/2021

Durable responses observed with COM701 in combination with Opdivo® including a confirmed complete response in a patient with prior progression on Opdivo®

COM701 monotherapy demonstrates signals of antitumor activity supporting the potential role of PVRIG inhibition in patients who have exhausted all available standard therapies

Data across tumor types and unresponsive patient populations further support Compugen's clinical approach with double and triple combination trials evaluating PVRIG, TIGIT and PD-L1 checkpoints

HOLON, Israel, Feb. 25, 2021 /PRNewswire/ -- **Compugen Ltd.** (Nasdaq: CGEN), a clinical-stage cancer immunotherapy company and a leader in predictive target discovery, reported today updated data from its Phase 1 dose escalation and expansion study of COM701 as a monotherapy, and in a dose escalation combination study with Opdivo® (nivolumab). COM701 is a first-in-class investigational therapeutic antibody targeting PVRIG, a novel immune checkpoint discovered computationally by Compugen.

"The data generated to date across our COM701 clinical program suggest that PVRIG may be an important immune checkpoint in patients who are unresponsive or refractory to currently available immunotherapies," said Anat Cohen-Dayag, Ph.D., President and CEO of Compugen. "We are highly encouraged by our updated results from the COM701 plus Opdivo® combination dose escalation, which now include a confirmed complete response in a patient with prior progression on Opdivo® and a previously reported patient with a durable confirmed partial response for almost a year. Combined with a disease control rate of 66.7% and ongoing durable signals of activity beyond or approaching one year in multiple patients and across indications, these results leave us increasingly confident that dual blockade of PVRIG and PD-1 may be key to driving anti-tumor immune responses in certain patient populations. Based on these encouraging results, we will be further evaluating this dual combination regimen in patients with ovarian, breast, endometrial and microsatellite-stable colorectal cancers with the initiation

of the COM701 and Opdivo® cohort expansion study in the second quarter of 2021, as part of our collaboration with Bristol Myers Squibb."

Dr. Cohen-Dayag continued, "Our monotherapy cohort expansion study was an important milestone in our COM701 monotherapy evaluation. This data, together with data from our previously reported dose escalation study, which includes a confirmed partial response with treatment ongoing for over one year as of our new data cutoff date, demonstrate durable signals of antitumor activity in tumor types typically unresponsive to immune checkpoint inhibitors, including patients with prior progression on these treatments. We will leverage these data, along with future data from our ongoing correlative assessments of biological samples from patients, to inform our clinical approach and next steps as we execute across our broad combination strategy, which includes dual and triple blockade regimens of COM701 with TIGIT and PD-1. Importantly, as the only company with wholly owned clinical candidates targeting both PVRIG and TIGIT, we are uniquely capable and on track to conduct this comprehensive evaluation of the synergistic blockade of the DNAM axis with PD-1, and we look forward to continued progress in potentially expanding the reach of immunotherapy."

Data highlights from the Phase 1 dose escalation studies as of the data cutoff of December 14, 2020 include:

COM701 and Opdivo® combination dose escalation arm:

- In 15 patients with a median of five prior anticancer therapies (range of 2-10), COM701 in combination with Opdivo® was well-tolerated with no reported dose-limiting toxicities up to the fifth and final dose cohort of COM701 20 mg/kg and Opdivo® 480 mg, both IV Q4 weeks.
- The disease control rate (DCR) was 66.7% (N=10) with best responses of complete response (CR) 6.7% (N=1), partial response (PR) 6.7% (N=1) and stable disease (SD) 53.3% (N=8).
- A patient with anal squamous cell carcinoma with confirmed SD as reported at American Association for Cancer Research (AACR) 2020, now with confirmed CR and remains on treatment at 79 weeks. This patient progressed on Opdivo® prior to enrolling in our study.
- A patient with microsatellite stable (MSS)-colorectal cancer with durable confirmed partial response previously reported at AACR 2020 remained on study treatment at 44 weeks.
- Durable responses of confirmed SD of six months or more in three patients. One patient with renal cell carcinoma remains on treatment at 58 weeks, and one patient with non-small cell lung cancer (NSCLC) (squamous) who failed prior treatment with immune checkpoint inhibitors remained on treatment at 36 weeks, and one patient with endometrial cancer remained on treatment at 46 weeks.

COM701 monotherapy arm dose escalation update since AACR 2020:

- The patient with primary peritoneal cancer (platinum resistant, MSS) with durable confirmed partial response remains on study treatment at 62 weeks.
- The patient with pancreatic cancer, refractory to all three prior lines of standard of care (SOC) therapy with durable confirmed SD was on study treatment for 31 weeks.

Data highlights from the monotherapy expansion cohort as of the data cutoff of December 14, 2020 include:

- 20 patients enrolled in biomarker and data informed indications; four patients of each: endometrial cancer, NSCLC, ovarian cancer, breast cancer and colorectal cancer.
- Six of the 20 patients (30%) had best responses of SD, one patient with endometrial cancer, three patients with NSCLC and two patients with ovarian cancer.
- Two patients with SD remain on treatment as of the data cutoff date; one patient with NSCLC who had >3 prior lines of SOC therapy; including prior treatment with immune checkpoint inhibitors with treatment ongoing at 26 weeks, and one patient with ovarian cancer with treatment ongoing at 20 weeks.
- Two additional patients remain on treatment as of the data cutoff date.
- No new safety findings were observed.

Additional clinical data and initial correlative assessments of biological samples from patients are planned to be presented at the American Society of Clinical Oncology 2021 annual meeting, to which an abstract was submitted.

Opdivo® is a registered trademark of Bristol Myers Squibb.

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. Compugen'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. Compugen's therapeutic pipeline also includes early stage immunoncology programs focused largely on myeloid targets. Compugen is headquartered in Israel, with offices 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.

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, including but not limited to statements related to the potential importance of the PVRIG checkpoint and dual blockade of PVRIG and PD-1 in treating patients, the expected initiation of the COM701 and Opdivo® cohort expansion study in the second quarter of 2021, and the potential and expected timing and results of future clinical data and results, 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. 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 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.

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