Compugen's COM701 (anti-PVRIG) in Dual and Triple Combination Demonstrates Preliminary Durable Anti-Tumor Activity and Immune Activation in Patients with Platinum Resistant Ovarian Cancer

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- COM701 in combination with nivolumab ± BMS-986207 (anti-TIGIT) in heavily pretreated patient population, resulted in encouraging durable confirmed partial responses (overall response rate 20% (n=20) triple study, 10% (n=20) dual study and disease control rate (45%) for both), supported by immune activation with a favorable safety and toxicity profile
- Three of the patients responded to triplet therapy for at least 9 months as of the data cut-off date and all four triplet responders continue treatment
- Anti-tumor activity with confirmed partial responses reported in diverse histologies, with majority (5 out of 6 responders in the two combinations) in the hardest to treat high-grade serous adenocarcinoma histology which is typically less responsive to immune checkpoint inhibitors

HOLON, Israel, Dec. 6, 2022 /PRNewswire/ -- Compugen Ltd. (Nasdaq: CGEN), a clinical-stage cancer immunotherapy company and a pioneer in computational target discovery, announced today publication of ePosters by ESMO Immuno-Oncology Congress 2022 (ESMO-IO), showing that Compugen’s COM701 (anti-PVRIG) in dual and triple combination with nivolumab ± BMS-986207 (anti-TIGIT) demonstrated preliminary durable anti-tumor activity and immune activation in patients with platinum resistant ovarian cancer with a favorable safety and toxicity profile.

The Company plans to host an investor conference call and webcast tomorrow, Wednesday, December 7, 2022, at 8:30 AM ET to review this data and data from a small cohort of metastatic NSCLC patients treated with COM701 ±
nivolumab planned to be presented at ESMO-IO, December 8, 2022, Geneva, Switzerland. ePosters are available today on the ESMO-IO virtual platform, in the e-Poster section and the publication section of Compugen's website.

“There are few effective and tolerable treatment options for patients with platinum resistant ovarian cancer,” said John W. Moroney, M.D., Associate Professor of Gynecologic Oncology in the Dept. of Obstetrics and Gynecology at the University of Chicago. "It is both exciting and a privilege to see heavily pre-treated, chemotherapy refractory patients experience durable responses with this novel PVRIG/TIGIT/PD-1 immune checkpoint targeting combination. We observed deep and durable responses with minimal toxicity. For example, several of our responders continue to maintain full-time employment of more than 6 months into their enrollment. I’m interested in participating in further clinical development of this targeted combination."

Oladapo Yeku, M.D., Ph.D., FACP, Assistant Professor of Medicine, Harvard Medical School, and Director of Translational Research, Gynecologic Oncology Program, Massachusetts General Hospital, Boston, MA, added, "It is encouraging to see anti-tumor activity in these heavily pretreated heterogeneous platinum resistant ovarian cancer patients, with a disease control rate of 45% following both dual and triple combination treatment. The combination of drugs was well tolerated with a favorable safety profile consistent with what has previously been reported for COM701 with nivolumab ± BMS-986207. Because of the anti-tumor activity and tolerability of the combination, our patients on the study reported an improvement in quality of life. I look forward to seeing the further development of COM701 combinations in patients with platinum resistant ovarian cancer."

Anat Cohen-Dayag, Ph.D., President, and CEO of Compugen, continued, "I am delighted to see that patients with hard-to-treat tumor types, who typically do not respond to or show low response rates to immunotherapy, gain benefit from COM701 as part of a dual and triple combination regimen. In November this year at the SITC conference, we presented anti-tumor activity with responses in MSS-CRC patients with liver metastases, with a clear support of a COM701 mediated effect. Today we published compelling responses from preliminary data in platinum resistant ovarian cancer patients, including a patient who had 7 prior lines of treatment and progressed on nivolumab, and on this study experienced a confirmed partial response after treatment with the dual combination of COM701 and nivolumab. In addition, 3 patients responded to triple combination therapy who are ongoing on study treatment for at least 9 months, including a patient with more than 90% reduction in tumor target lesions."

Dr. Cohen-Dayag, added, "The data suggest a COM701 mediated mechanism of action, which could lead to the responses demonstrated by COM701 combinations. We have demonstrated that PVRIG blockade is associated with driving T cells into the tumor microenvironment, potentially sensitizing the tumors to PD-1 and/or TIGIT blockade and inducing a potent immune activation generally less typical with checkpoint inhibitors in such tumor types. While it is challenging to compare efficacy of the triple and dual combination arms given the small number of patients, the increase in response rate combined with the duration of response does suggest greater benefit with
triple treatment, in line with our pre-clinical and translational clinical data. While the studies, including the biomarker and translational work, are still ongoing, the totality of the data, consisting of the disease control rates, the durability of responses, the supportive translational data, and the favorable safety profile, are encouraging considering these hard-to-treat cancers in which the patients have been extensively pretreated. We are looking forward to discussing the data being presented at ESMO-IO, during our investor call tomorrow, December 7, 2022.”

Next Steps

Based on the data reported in the different studies, Compugen is planning to pursue two studies, with the purpose to strengthen the data it has already published and to build a path to future registration studies:

- The first, in up to 20 patients with metastatic MSS-CRC, immune checkpoint inhibitor naïve patients with ≤ 2L of prior therapy, treated with a triple combination of Compugen's anti-PVRIG, COM701, and its own anti-TIGIT, COM902, and pembrolizumab. Enrolment is expected to be completed in 2023.
- The second is a follow up study currently under design in platinum resistant ovarian cancer immune checkpoint inhibitor naïve patients.

Compugen expects to share initial findings by the end of 2023.

The ePosters are published today on the ESMO-IO virtual platform in the e-Poster section, and the publication section of Compugen's website.

To access the Wednesday, December 7, 2022, 8:30 am ET live investor conference call by telephone, please dial 1-866-744-5399 from the U.S., or +972-3-918-0644 internationally. The call will be available via live webcast through Compugen's website, located at the following link. Following the live webcast, a replay will be available on the Company's website.

Background

Key findings from poster: “Triple blockade of the DNAM-axis with COM701 + BMS-986207 + nivolumab demonstrates preliminary antitumor activity in patients with platinum resistant OVCA.” (NCT04570839), with a cut-off date of November 23, 2022, include:

- In 20 patients who had exhausted all standard therapies, with a median number of 4 prior therapies, the triple combination demonstrated:
  - Encouraging overall response rate of 20%, with 4 confirmed partial responses, out of which 3 are responding for at least 9 months. All 4 responders are still on study treatment at the data cut-off date, therefore median duration of response has not been reached.
Disease control rate of 45% (4 confirmed partial responses, 5 stable disease)
Low pre-treatment PD-L1 expression in 2 of the responders (CPS <1 and 3), analysis of the other responders is still ongoing
Translational assessment of peripheral blood, including profiling of cytokines and circulating immune cells, showed a pharmacodynamic activation of the immune system
Most frequent treatment related adverse events grade 1/2, no grade 4/5 treatment related adverse events

55% of the patients had high-grade serous adenocarcinoma, including three of the responders

Key findings from poster: "COM701 in combination with nivolumab demonstrates preliminary antitumor activity in patients with platinum resistant epithelial ovarian cancer" (NCT03667716) with a cut-off date of November 23, 2022, include:

- In 20 patients who had exhausted all standard therapies, with a median number of 6 prior therapies, the dual combination demonstrated:
  - Encouraging overall response rate of 10%, with 2 partial responses and 1 ongoing at the data cut-off date
  - Disease control rate of 45% (2 confirmed partial responses, 7 stable disease)
  - Translational assessment of peripheral blood, showed a pharmacodynamic activation of the immune system
  - One patient with a partial response supported by increased infiltration of CD8 cells into the tumor microenvironment, had high grade serous adenocarcinoma, 7 prior lines of treatment including best response of progressive disease on the combination of nivolumab and lucitanib (an investigational agent)
  - Most frequent treatment related adverse events grade 1/2, no grade 4/5 adverse events
- 65% of the patients had high-grade serous adenocarcinoma, including the two responders

About Compugen

Compugen is a clinical-stage therapeutic discovery and development company utilizing its broadly applicable predictive computational discovery capabilities to identify new drug targets and biological pathways for developing cancer immunotherapies. Compugen has developed two proprietary product candidates: COM701, a potential first-in-class anti-PVRIG antibody and COM902, a potential best-in-class antibody targeting TIGIT for the treatment of solid tumors. Compugen currently has one partnered program, namely AZD2936, a TIGIT/PD-1 bispecific derived from COM902, that is in Phase 2 development by AstraZeneca through a license agreement for the development of bispecific and multi-specific antibodies. In addition, the Company’s therapeutic pipeline of early-stage immuno-
oncology programs consists of programs aiming to address various mechanisms of immune resistance, including myeloid targets. The most advanced program, COM503 is about to enter pre-IND enabling studies. COM503 is a potential first-in-class, high affinity antibody targeting cytokine biology to enhance anti-tumor immunity in a differentiated manner. 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.

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 using 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 enrolment in metastatic MSS-CRC that is expected to be completed in 2023, statements that Compugen's plans to pursue two studies, with the purpose to strengthen the data it has already published and to build a path to future registration studies, including the design of such studies and timing of any announcements relating thereto. 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: the effect of the global COVID-19 pandemic may negatively impact the global economy and may also adversely affect Compugen's business and operations; clinical trials of any product candidates that Compugen, or any current or future collaborators, may develop may fail to satisfactorily demonstrate safety and efficacy to the FDA, and Compugen, or any collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates; 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. Compugen's approach to the discovery of therapeutic products is based on its proprietary computational target discovery infrastructure, which is unproven clinically; and Compugen does not know whether it will be able to discover and develop additional potential product candidates or products of commercial value. 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:
Yvonne Naughton, Ph.D.
Head of Investor Relations and Corporate Communications
Email: ir@cgen.com
Tel: +1 (628) 241-0071


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