

**ABSTRACT #4597 & 4574**

**EMBARGO: SATURDAY, JUNE 4, 2:15 PM ET**

CG Oncology Presents New Clinical Data on Two Ongoing Programs at The American Society of Clinical Oncology (ASCO) 2022 Annual Meeting

- 92% (n=22/24) of Evaluable Patients Achieved Complete Response (CR) at the Initial 3-Month Timepoint From the Phase 2 Clinical Trial of CG0070, an Oncolytic Immunotherapy, in Combination with KEYTRUDA® (pembrolizumab) for NMIBC Unresponsive to BCG -
- Promising Preliminary Efficacy and Safety Data From the Phase 1b/2 study of CG0070 in Combination with OPDIVO® (nivolumab), as a Neoadjuvant Immunotherapy for MIBC in Cisplatin-Ineligible Patients -

June 4, 2022, 2:15 PM Eastern Standard Time

IRVINE, Calif. (BUSINESSWIRE)--[CG Oncology, Inc.](#), a clinical-stage biotechnology company focused on developing oncolytic immunotherapies for patients with advanced cancer, today announced interim data on two ongoing clinical studies will be presented at The American Society of Clinical Oncology (ASCO) 2022 Annual Meeting.

The first poster presentation reports on efficacy and safety data from a global Phase 2 study (CORE1) of CG0070 in combination with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab), for the treatment of patients with Non-Muscle-Invasive Bladder Cancer (NMIBC) unresponsive to Bacillus Calmette-Guerin (BCG).

The second poster presentation centers on a Phase 1b/2 study (CORE2) of CG0070 in combination with OPDIVO® (nivolumab), as a neoadjuvant immunotherapy for Muscle-Invasive Bladder Cancer (MIBC) in cisplatin-ineligible patients. This investigator-initiated study led by Dr. Roger Li at Moffitt Cancer Center in Tampa, Florida will summarize promising early data on safety and efficacy with the combination in this MIBC patient population.

"We're excited to present these results at ASCO, which continue to support CG0070's promise in patients with bladder cancer unresponsive to BCG, a difficult-to-treat patient population," said Arthur Kuan, Chief Executive Officer, CG Oncology. "We hope to see continued positive results for CG0070 in combination with pembrolizumab in NMIBC patients unresponsive to BCG, and also, in future studies, show combination activity with nivolumab in MIBC patients who have limited treatment options."

"Using an oncolytic virus to first engage an immune response and then amplifying that response with immune checkpoint blockade has shown exciting results in bladder cancer," said Roger Li, MD, lead study investigator and urologic oncologist at Moffitt Cancer Center. "CG0070 is a potential game changer to combat BCG-unresponsive bladder cancer."

**Abstract ID 4597: CORE1: Phase 2, single-arm study of CG0070 combined with pembrolizumab in patients with nonmuscle-invasive bladder cancer (NMIBC) unresponsive to bacillus Calmette-Guerin (BCG)**

The preliminary data for CORE1 adds to that presented at the [American Urological Association \(AUA\)](#) and the [American Association of Cancer Research \(AACR\)](#) Annual Meetings earlier this

year and continues to show both promising early anti-tumor activity and tolerability of CG0070 in combination with pembrolizumab for patients with BCG unresponsive NMIBC.

- As of the interim analysis, based on a data cutoff on May 13, 2022, 24 patients were evaluable for efficacy with a minimum of 3 months follow up.
- 92% of patients evaluable for efficacy (n=22/24) have achieved complete response (CR) at the initial 3-month timepoint. Of those patients evaluable for CR at additional timepoints, 88% (n=16) have also maintained a CR through 6 months, 82% (n=11) through 9 months and 75% (n=8) at the 12-month assessment.
- The combination has been generally well tolerated with the most common treatment related adverse events limited to transient grade 1-2 local genitourinary symptoms including pollakiuria, bladder spasm, dysuria, fatigue, nocturia, hematuria, chills, and immune-related adverse events including hyperglycemia and hypothyroidism consistent with the safety profiles previously established for each agent alone in previous studies.

Under a previously announced clinical collaboration with Merck (known as MSD outside the US and Canada) relating to the investigation of CG0070 in combination with pembrolizumab, the goal of CORE1, which will enroll up to 35 patients, is to evaluate the safety and efficacy of CG0070 plus pembrolizumab for the treatment of NMIBC unresponsive to BCG.

More information about the study can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT04387461).

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

### **Abstract ID 4574: Preliminary results from phase Ib/II neoadjuvant CG0070 and nivolumab (N) for cisplatin (C)-ineligible muscle invasive bladder cancer (MIBC)**

Thus far, a CR rate of 54% (n=7/13) has been observed with 12 pathological CR at cystectomy and 1 clinical CR in a patient who refused cystectomy. Treatment has generally been well tolerated with no patient discontinuing treatment due to treatment related toxicity.

An investigator-initiated study being conducted at Moffitt Cancer Center, the single-arm trial will enroll up to 30 patients with MIBC with no evidence of distant metastases prior to radical cystectomy. Primary endpoints of the trial are safety and pathological complete response rate.

More information about the study can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT04610671).

### **About CG Oncology**

CG Oncology is a clinical-stage biotechnology company focused on developing the next evolution of oncolytic immunotherapy for patients with advanced cancer. Our lead candidate, CG0070, is a selective oncolytic immunotherapy in a Phase 3 trial with CG0070 as a monotherapy for the treatment of BCG-unresponsive NMIBC, and a combination Phase 2 study of CG0070 with KEYTRUDA® (pembrolizumab) in the same indication. Other types of bladder cancer are being evaluated with CG0070 in combination with OPDIVO® (nivolumab), and additional indications in other solid tumors are being pursued with CG0070 in combination with other immune checkpoint inhibitors. At CG Oncology, we aim to take the next evolutionary step in delivering innovative cancer care to millions of patients in need worldwide. Learn more at [www.cgoncology.com](http://www.cgoncology.com). Follow us on Twitter @cgoncology.

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