CG Oncology Presents New Phase 2 Data with cretostimogene grenadenorepvec in Combination with pembrolizumab in Non-Muscle Invasive Bladder Cancer Unresponsive to Bacillus Calmette-Guérin

Nov 10, 2022

– 88% (n=28/32) of Evaluable Patients Achieved Complete Response at the Initial 3-Month Timepoint from the Phase 2 Clinical Trial of CG0070 in Combination with KEYTRUDA® (pembrolizumab) for NMIBC Unresponsive to BCG –

– CG0070 in Combination with KEYTRUDA was Well Tolerated with Promising Efficacy and Safety Data –

IRVINE, Calif., November 10, 2022 – CG Oncology, Inc., an oncolytic immunotherapy company focused on developing novel therapeutics for patients with urologic cancers, today announced new updated data from its 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-Guérin (BCG).

The results were announced in an oral presentation at the Society for Immunotherapy of Cancer (SITC) Annual Meeting, held virtually and in person in Boston, MA.

"We're excited to present these results, 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 are seeing continued positive results for CG0070 in combination with pembrolizumab in NMIBC patients unresponsive to BCG. Enrollment in this study is now completed, and data readout on all patients through a minimum of 12 months is expected in 2023."

Summary of Interim Clinical Results

Abstract #666 – Phase 2, Single Arm Study of CG0070 Combined with Pembrolizumab in Patients with Non-Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Bacillus Calmette-Guerin (BCG)

The new data for CORE1 adds to that presented at the ASCO 2022 Annual Meeting 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 October 10, 2022, 32 patients were evaluable for efficacy with a minimum of 3-month follow up.
- 88% of patients evaluable for efficacy (n=28/32) have achieved complete response (CR) at the initial 3-month timepoint. Of those patients evaluable for CR at additional timepoints, 88% (n=23/26) have also maintained a CR through 6 months, 86% (n=18/21) through 9 months and 73% (n=11/15) at the 12-month assessment.
- CG0070 in combination with pembrolizumab has been generally well tolerated with the adverse event profile consistent with that observed in prior studies of each agent alone. The most common treatment-related adverse events reported include transient grade 1-2 local genitourinary symptoms.

"There is a critical unmet need for efficacious bladder-sparing therapies for patients with BCG-unresponsive bladder cancer," said Roger Li, MD, lead study investigator and urologic oncologist at Moffitt Cancer Center. "CG0070 has continued to show very promising results, more than doubling CR rates previously seen with immune checkpoint inhibitors. With a unique dual-mechanism of action that first engages an immune response and then amplifies that response with immune checkpoint blockade, this novel combination of CG0070 with pembrolizumab could potentially change the outlook for patients with BCG-unresponsive bladder cancer."

About the CORE1 Study

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, CORE1, which has completed enrollment of 35 total 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 (NCT04387461).

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

About CG0070

Our lead candidate, CG0070, is an intravesically delivered oncolytic immunotherapy agent in a Phase 3 trial for the treatment of BCG-unresponsive non-muscle invasive bladder cancer. CG0070 is also in a Phase 2 study in combination with KEYTRUDA® (pembrolizumab) in the same indication. Other types of bladder cancer are being evaluated with CG0070 in combination with OPDIVO® (nivolumab).

About CG Oncology

CG Oncology is an oncolytic immunotherapy company focused on developing bladder-saving therapeutics for patients with urologic cancer. At CG Oncology, we see a world where urologic cancer patients can benefit from our innovative therapies to live and work with dignity and an enhanced quality of life. To learn more, visit www.cgoncology.com. Follow us on Twitter @cgoncology.

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