

Carina Biotech to Present Details of Planned Phase 1/2a Clinical Trial of LGR5-Targeted CAR-T Cell Therapy Candidate CNA3103 for Metastatic Colorectal Cancer at 2023 ASCO Annual Meeting

- First in human, multicenter, open label, Phase 1/2a dose escalation and expansion study to determine the safety of and overall best response to CNA3103 in subjects with mCRC
- Phase 1 segment of the trial to follow a BOIN design with a minimum of three consecutively enrolled subjects per cohort

ADELAIDE, AUSTRALIA, April 2, 2023 - **Carina Biotech** (Carina), a cell therapy immuno-oncology company, today announced a poster presentation showcasing its planned Phase 1/2a clinical trial of its LGR5-targeted CAR-T cell therapy candidate CNA3103 in patients with metastatic colorectal cancer (mCRC) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting that will take place in Chicago, Illinois on June 2-6.

“We look forward to sharing the innovative design of our planned Phase 1/2a trial with the oncology community at the upcoming 2023 ASCO,” remarked Deborah Rathjen, Carina’s Chief Executive Officer. “We are currently activating sites in Australia and anticipate commencing patient dosing before the end of the second quarter.”

The Phase 1/2a clinical trial is designed to enrol up to 44 patients with metastatic disease failing prior lines of chemotherapy and who express LGR5 on their cancer cells. The Phase 1 segment of up to 24 patients will follow a BOIN (Bayesian Optimal Interval) design and ascending CAR-T cell doses will be administered to cohorts of three patients each, to assess the safety and tolerability of CNA3103, and to determine its optimal dose. The subsequent Phase 2 segment will enrol 20 patients at the optimal dose, in both Australia and the U.S., to characterize the activity of CNA3103, in terms of anti-tumor response, duration of response and time to disease progression.

Further details about the Phase 1/2a trial (NCT05759728) can be found at clinicaltrials.gov.

Poster Presentation Details

Title: A phase 1/2a, multicenter, open-label study of CNA3103 (LGR5-targeted, autologous CAR-T cells) in patients with metastatic colorectal cancer (mCRC)

Lead Author: José Iglesias, MD, Carina’s Chief Medical Officer

Session Type/Title: Poster Session - Gastrointestinal Cancer—Colorectal and Anal

Session Date and Time: Monday June 5, 2023 from 8:00 AM CDT - 11:00 AM CDT

Published Abstract Number: TPS3632

About CNA3103

Carina’s proprietary CNA3103 CAR-T cell targets LGR5, a cancer stem cell marker that is highly expressed on advanced colorectal cancer and some other cancers. In colorectal cancer patients, LGR5 expression has been correlated with poor prognosis. Cancer stem cells are a small sub-population of cells within a tumor with the ability to self-renew, differentiate into the many cell types of a tumor, initiate new tumors, and resist chemotherapy and radiotherapy (leading to relapses). By targeting cancer stem cells, it is hoped that this therapy will reduce the tumor’s ability to generate new cancer cells, resulting in durable tumor suppression and preventing the relapses that are very common in patients with colorectal cancer. Carina’s pre-clinical studies of CNA3103 have shown promising

results with complete tumor regression and no tumor recurrence following a single administration. CNA3103 has also demonstrated impressive tumor access, prolonged survival, and rejection of tumor rechallenge.

About Carina Biotech

Immuno-oncology company Carina Biotech is developing CAR-T and other adoptive cell therapies for the treatment of solid cancers. In addition to its LGR5-targeted CAR-T cell therapy CNA3103 for advanced colorectal cancer, Carina has a deep pipeline of CAR-T programs.

Using its proprietary chemokine receptor platform, Carina aims to improve access to and infiltration of solid cancers by CAR-containing cells, resulting in more potent and specific cancer killing and reduced off-target effects.

Carina also has a fully integrated, proprietary manufacturing process that has both reduced manufacturing time and improved CAR-T cell quality, capable of delivering robust “serial-killing” CAR-T cells to patients.

For more information please contact:

Deborah Rathjen, PhD
CEO & Managing Director
Carina Biotech
+61 418 160 425
deborah@carinabiotech.com

Rudi Michelson
Monsoon Communications
+61 (0)3 9620 3333
rudim@monsoon.com.au

Stephanie Carrington
ICR Westwicke
+1 646 277 1282
stephanie.carrington@westwicke.com