

News Release

June 14, 2021
Carna Biosciences, Inc.

Carna Announces Dosing of the First Patient in a First-in-Human Phase 1 Study of AS-0141

Carna Biosciences, a clinical-stage biopharmaceutical company focusing on the discovery and development of innovative therapies to treat serious unmet medical needs, announces today that the first patient has been dosed in the Phase 1 clinical trial of AS-0141, a potent, selective, and orally bioavailable small molecule inhibitor of CDC7 kinase. The Phase 1 study of AS-0141 is being conducted in Japan in patients with unresectable, advanced, recurrent, or metastatic solid tumors. The study consists of two parts, a dose escalation and an expansion. The primary objectives of the dose escalation part are to assess the safety and tolerability of AS-0141 as well as to measure its pharmacokinetics and pharmacodynamics. The second portion of the Phase 1 study is the expansion part, in which the patients will receive AS-0141 to further evaluate the safety and preliminary anti-tumor activity to determine a recommended Phase II dose (RP2D).

Kohichiro Yoshino, Ph.D., President and Chief Executive Officer at Carna Biosciences commented, “AS-0141, a CDC7 inhibitor originally discovered by Carna, has a unique mechanism from the existing anticancer drugs and is expected to become an innovative drug to contribute to the patients who suffer from cancer.”

Akinori Arimura, Ph.D., Head of Clinical Development at Carna Biosciences and Chief Development Officer at CarnaBio USA said, “AS-0141 strongly inhibits CDC7 kinase that regulates cell cycle transitions and is expected to show substantial anti-tumor activity in various cancers. Based on the preclinical data, we have designed the clinical trial of AS-0141 to advance efficiently, focusing on the patients who are likely to respond to AS-0141. We hope to deliver a new therapeutic option to patients with cancer.”

About AS-0141

CDC7 (cell division cycle 7) is a serine-threonine kinase that plays a critical role in DNA synthesis and is required for the activation of DNA replication origins throughout the S phase of the cell cycle. Inhibition of CDC7 in cancer causes lethal S phase or M phase progression, whereas normal cells survive, most likely through induction of cell cycle arrest at the DNA replication checkpoint. It has been reported in the literature that CDC7 is overexpressed in many types of cancers, therefore CDC7 is an attractive target for cancer drug development. Carna has successfully identified a selective and potent CDC7 inhibitor, AS-0141, with a unique mechanistic slow off-rate.

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