

News Release

February 22, 2021 Carna Biosciences, Inc.

Carna announces completion of PMDA review for a clinical trial notification to initiate clinical trial 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 Pharmaceuticals and Medical Devices Agency (PMDA) review for the clinical trial notification of AS-0141 to initiate phase I study in solid tumors has been successfully completed.

AS-0141 is a potential first-in-class, potent, selective, and orally bioavailable small molecule inhibitor of CDC7 kinase. Carna plans to initiate the Phase 1 study in solid tumors in Japan in the first half of 2021. The Phase 1 clinical trial of AS-0141 is designed to assess the safety and tolerability of AS-0141 in advanced solid tumors, as well as to identify the recommended Phase 2 dose.

"We are excited to initiate a First-in-Human study of AS-0141 in Japan soon. AS-0141 has a potential to become the first-in-class CDC7 inhibitor and our goal is to deliver this innovative therapy to patients who suffer from cancer as soon as possible," said Kohichiro Yoshino, Ph.D., President and Chief Executive Officer at Carna Biosciences.

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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