CARNA BIOSCIENCES

News Release

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Carna Biosciences, Inc.

Carna Announces Clearance of IND to Initiate Phase 1b Study of AS-1763 in the U.S.

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 it has received a “Study May Proceed” letter from Food and Drug Administration (FDA) for an Investigational New Drug (IND) application to initiate a Phase 1b study of AS-1763 in the U.S.

AS-1763, an investigational small molecule drug designed to non-covalently inhibit Bruton's tyrosine kinase (BTK) in a highly selective manner, is currently under development for treating patients with chronic lymphocytic leukemia (CLL) and other B cell malignancies with acquired resistance to covalent BTK inhibitors. The Phase 1 single ascending dose study in healthy volunteers was conducted in the Netherlands in 2021, in which AS-1763 was well-tolerated and demonstrated a favorable safety, pharmacokinetic and pharmacodynamic profile at all dose levels. The Phase 1b study of AS-1763 in the U.S. will be conducted in patients with previously treated CLL, small lymphocytic lymphoma (SLL), and B-cell non-Hodgkin lymphoma (B-cell NHL) and consists of two parts: dose escalation and dose expansion. The primary objective of the dose escalation part is to determine the maximum tolerated dose (MTD) and dose-limiting toxicities (DLTs) of AS-1763. Safety, tolerability, pharmacokinetics, and preliminary efficacy will be also evaluated as secondary objectives. The dose expansion part will further recruit patients with previously treated CLL/SLL or B-cell NHL to explore safety, efficacy, and pharmacokinetics of AS-1763 at multiple doses selected in the dose escalation part, and the recommended phase 2 dose (RP2D) will be determined. The first patient is expected to be dosed in the second half of 2022.

“The Phase 1b study of AS-1763 is the first clinical study which will be conducted by our U.S. clinical development team. We are pleased that we have reached our first goal to initiate clinical studies for cancer in the U.S. We intend to accelerate the development of AS-1763, a next generation BTK inhibitor, and hope to contribute to the patients who suffer from cancer,” said Kohichiro Yoshino, Ph.D., President and Chief Executive Officer at Carna Biosciences.

About AS-1763

AS-1763 is a highly selective, orally bioavailable, non-covalent inhibitor of both the wild type and C481S mutant BTK for the treatment of CLL and other B cell malignancies. First generation covalent BTK inhibitors including ibrutinib are key therapeutic options for patients with B cell malignancies. However, patients are reported to develop resistance during the treatment due to substitution of cysteine residue at 481 position with serine (C481S mutation) in BTK, which prevents the covalent binding of the first generation irreversible BTK inhibitors. In in vitro experiments, AS-1763 significantly abrogates cell proliferation in both wild type and C481S mutant BTK lymphoma cells, strongly suggesting AS-1763 will be a new therapeutic option for treating patients with B cell malignancies both having wild type and C481S mutation in BTK.

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