CARNA BIOSCIENCES

News Release

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Carna Biosciences, Inc.

Carna Announces Initiation of BA part of Phase 1 Clinical Study for AS-1763

Carna Biosciences, a clinical-stage biopharmaceutical company focusing on the discovery and development of innovative therapies to treat serious unmet medical needs, announces the initiation of the bioavailability (BA) part of the Phase 1 clinical study for AS-1763, an investigational small molecule drug designed to non-covalently inhibit Bruton's tyrosine kinase (BTK) in a highly selective manner. The preclinical study of AS-1763 demonstrated that the compound is capable of potently inhibiting both wild and C481S mutant BTK, and it 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 single ascending dose (SAD) part, a randomized, double-blind, placebo controlled, oral single ascending dose study in healthy male and female adult subjects, was conducted in the Netherlands in H1 2021, in which AS-1763 was well-tolerated without any safety concerns and demonstrated a favorable pharmacokinetic profile. On December 2 (CEST), Carna initiated the BA part of the Phase 1 study for AS-1763 to evaluate the relative bioavailability of the newly developed formulation in comparison with the simple formulation used in the SAD part. The newly developed formulation will be used in a Phase 1b study in patients.

Carna is currently preparing for a pre-IND meeting with FDA (Food and Drug Administration) to file an Investigational New Drug (IND) application to initiate a Phase 1b study of AS-1763 in patients with chronic lymphocytic leukemia (CLL) and other B cell malignancies in the U.S. in 2022.

About AS-1763

AS-1763 is a highly selective, orally bioavailable, non-covalent inhibitor of both the wild type and C481S mutant Bruton’s tyrosine kinases (BTK) for the treatment of chronic lymphocytic leukemia (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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