

News Release

January 5, 2022
Carna Biosciences, Inc.

Submission of Investigational New Drug Application for AS-1763 (BN102) in China by BioNova

Carna Biosciences, a clinical-stage biopharmaceutical company focusing on the discovery and development of innovative therapies to treat serious unmet medical needs, announces that BioNova Pharmaceuticals Limited (BioNova), the licensee of AS-1763 in Greater China territory, has submitted an investigational new drug (IND) application for AS-1763 (BioNova's development code: BN102) for the treatment of Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) and B-cell Non-Hodgkin Lymphoma (NHL) to the China National Medical Products Administration (NMPA).

AS-1763, identified by Carna, is an investigational small molecule drug designed to non-covalently inhibit Bruton's tyrosine kinase (BTK) in a highly selective manner. Carna retains worldwide development and commercialization rights to AS-1763 excluding Greater China and is planning to initiate 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 the preclinical study, 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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