

News Release

March 18, 2022
Carna Biosciences, Inc.

Carna Receives the First Milestone Payment from BioNova following the Clearance of Investigational New Drug Application for AS-1763 (BN102) in China

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 received an approval for its investigational new drug (IND) application for AS-1763 (BioNova's development code: BN102) from Center of Drug Evaluation (CDE) of National Medical Products Administration (NMPA) to conduct clinical trials in patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) and B-cell Non-Hodgkin Lymphoma (NHL) in China. Carna receives the first milestone payment of \$500,000 from BioNova under a license agreement in March 2020 to grant BioNova exclusive rights to develop and commercialize AS-1763(BN102) in Greater China.

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. In the preclinical study, AS-1763 significantly abrogates cell proliferation in both wild type and C481S mutant BTK lymphoma cells, strongly suggesting that AS-1763 will be a new therapeutic option for treating patients with B cell malignancies both having wild type and C481S mutation in BTK. The worldwide development and commercialization rights to AS-1763 excluding Greater China are retained by Carna. Carna is conducting a Phase 1 study in healthy volunteers in Europe and plans to file an IND application with FDA (Food and Drug Administration) in the second quarter of 2022 to initiate a Phase 1b study of AS-1763 in patients with chronic lymphocytic leukemia (CLL) and other B cell malignancies. The Phase 1b study in the U.S. is expected to be initiated in the second half of 2022.

The milestone payment of \$500,000 from BioNova, not included in Carna's consolidated forecast for FY2022, is recognized as sales in the first quarter of FY2022.

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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