CARNA BIOSCIENCES

News Release

March 7, 2023
Carna Biosciences, Inc.

Carna Biosciences Regains Exclusive Development and Commercialization Rights to AS-1763 in Greater China

Carna Biosciences, a clinical-stage biopharmaceutical company focusing on the discovery and development of innovative therapies to treat serious unmet medical needs, today announced that it has regained the exclusive rights to develop and commercialize AS-1763 in Greater China from BioNova Pharmaceuticals Limited (BioNova). This decision to regain Greater China rights is a result of a strategic asset review by Carna considering the importance of Greater China territory in the global pharmaceutical market. Pursuant to the mutual termination agreement between BioNova and Carna, BioNova will transfer to Carna all regulatory documentation related to AS-1763 for China IND approval including all the other supporting data.

“We thank the BioNova team for their collaborative contributions to develop AS-1763 in Greater China. Our initial aim was to accelerate the global development of AS-1763 by initiating the clinical trials in China in advance of the other regions. Unfortunately, however, the COVID-19 pandemic interrupted many clinical development activities worldwide including China, causing a delay in our global development timeline. In the meantime, the first-patient-in is expected soon in the Phase 1b study in the U.S. and we reached the conclusion that regaining the worldwide rights will help accelerate the global development of AS-1763,“ said Kohichiro Yoshino, Ph.D., President and Chief Executive Officer at Carna Biosciences. "China has the second-largest pharmaceutical market in the world. We believe that regaining the development and commercialization rights in Greater China will enable Carna to facilitate our global partnering strategy and to deliver the highest possible value to our shareholders.”

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 March 2020, Carna granted BioNova exclusive rights to develop and commercialize AS-1763 in Greater China and received an upfront payment. In March 2022, Carna received the first milestone payment of $500,000 when BioNova received an approval for its investigational new drug (IND) application for AS-1763 from Center of Drug Evaluation (CDE) of National Medical Products Administration (NMPA).

Carna is preparing to initiate Phase 1b study of AS-1763 in the U.S. in patients with previously treated chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), and B-cell non-Hodgkin Lymphoma (B-cell NHL). The first-patient-in (FPI) is expected in Q2 2023.

About AS-1763

AS-1763 is a highly selective, orally bioavailable, non-covalent inhibitor of both the wild type and mutant BTKs for the treatment of CLL and other B cell malignancies. 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 reduces the efficacy of the covalent BTK inhibitors. In addition, the emergence of other types of resistance mutations to non-covalent BTK inhibitors including pirtobrutinib in development have been reported. AS-1763 potently inhibited both wild type and those mutant BTKs, strongly suggesting that AS-1763 will be a new therapeutic option for treating patients with B cell malignancies both having wild type and resistance mutations in BTK. Carna is advancing development of AS-1763 as a next-generation BTK inhibitor.

Contact:
Corporate Planning
Carna Biosciences, Inc.
TEL: +81-78-302-7075
https://www.carnabio.com/english/