

News Release

August 25, 2020
Carna Biosciences, Inc.

Carna announces the initiation of dosing in a First-in-Human Phase 1 study of AS-0871

Carna Biosciences, a biopharmaceutical company focusing on the discovery and development of innovative drugs targeting kinases, announces the dosing of the first subject in its Phase 1 clinical trial for AS-0871, an investigational small molecule drug designed to non-covalently inhibit Bruton's tyrosine kinase (BTK) with high selectivity targeting inflammatory and immune disorders.

The first subject was dosed with AS-0871 on August 25 (CET), after implementing various measures to secure the safety of volunteers and healthcare workers against COVID-19. Central Committee on Research Involving Human Subjects (CCMO) and the Ethics Committee approved a Clinical Trial Application (CTA) for AS-0871 in February 2020, but the First-in-Human study initially planned in the first quarter was rescheduled due to the COVID-19 pandemic in Europe.

The Phase 1 clinical study of AS-0871 is a randomized, double-blind, placebo controlled, oral single ascending dose ("SAD") study in healthy male and female adult subjects. The SAD study is being conducted in up to 64 subjects in the Netherlands and will assess the safety, tolerability, and pharmacokinetics of AS-0871 and will include measurement of its pharmacodynamics as a secondary endpoint (EudraCT 2019-004348-31). Preliminary results are expected in the first half of 2021.

"AS-0871 is a highly selective and non-covalent BTK inhibitor, potential to become a new treatment option for inflammatory and immune disorders. We plan to continue the clinical development of AS-0871 targeting BTK-related inflammatory and immune disorders, after obtaining safety and pharmacokinetics data in the SAD study," said Akinori Arimura, Ph.D., Head of Clinical Development at Carna Biosciences and Chief Development Officer at CarnaBio USA.

"We are proud that we have initiated our First-in-Human study of AS-0871 in this difficult environment, achieving an important milestone to become a clinical-stage biopharmaceutical company. We continue to focus on the discovery and development of innovative therapies to address the unmet medical needs of patients with serious diseases," said Kohichiro Yoshino, Ph.D., President and Chief Executive Officer at Carna Biosciences.

About AS-0871

Bruton's Tyrosine Kinase (BTK) is known to play a crucial role in multiple signaling pathways related to the immune responses in B-cells, macrophages, and mast cells, regulating the release of several proinflammatory mediators. The implication of BTK in a variety of pathological processes has been reported, and thus BTK has emerged as a promising target for inflammatory and immune disorders involving B-cell, macrophage, and mast cell activation. AS-0871 is a highly selective and non-covalent BTK inhibitor discovered by Carna, being developed for the treatment of inflammatory and immune disorders.

Contact:

Corporate Planning

Carna Biosciences, Inc.

TEL: +81-78-302-7075

<https://www.carnabio.com/english/>