

## News Release

January 25, 2023  
Carna Biosciences, Inc.

### **Carna Initiates Dosing in the MAD Part of Phase 1 Trial of AS-0871**

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 initiated dosing in its Phase 1 Multiple Ascending Dose (MAD) part of AS-0871 in healthy volunteers, an investigational small molecule drug designed to non-covalently inhibit Bruton's tyrosine kinase (BTK) with high selective profile targeting inflammatory and immune disorders.

The phase 1 MAD study of AS-0871 was initiated in December 2021 and consists of two parts: bioavailability (BA) part to evaluate the relative bioavailability of AS-0871 using new formulations and MAD part to evaluate the safety, tolerability, pharmacokinetic (PK) and pharmacodynamic (PD) of AS-0871 in multiple ascending dose study. The initiation of the MAD part follows the successful completion of the BA part, in which the new tablet formulation was shown to be safe and demonstrated good oral bioavailability.

The MAD part is designed to characterize the safety, tolerability, PK, and PD of 3 multiple ascending doses of AS-0871, after repeated dosing of AS-0871 for 14 days using a double blind, placebo-controlled, randomized design in 3 cohorts of 8 healthy subjects each. The results are expected in the second half of 2023.

In the completed phase 1 Single Ascending Dose (SAD) study, AS-0871 was shown to be safe and well-tolerated at all dose levels and demonstrated favorable pharmacokinetic profile. Pharmacodynamic study results of AS-0871 demonstrated that subjects who received AS-0871 showed dose proportional inhibitions in basophil and B-cell activations, and significant and sustained inhibitory effects were observed at 100 mg and above.

The partnering activity to find a licensing or co-development partner who will conduct the Phase 2 study of AS-0871 is underway, and Carna hopes to accelerate the development of AS-0871 and contribute to the patients who need better treatment options.

#### **About AS-0871**

AS-0871 is an investigational small molecule drug designed to bind non-covalently to Bruton's tyrosine kinase (BTK) with high selectivity, currently in development for inflammatory and immune disorders. In in vitro experiments, AS-0871 strongly inhibited B cell and basophil activation and suppressed production of inflammatory cytokines such as TNF- $\alpha$ , IL-17, MCP-1 and IL-6 in human blood. Oral administration of AS-0871 demonstrated the excellent therapeutic effects in a mouse model of collagen-induced arthritis. In addition, AS-0871 prevented IgE-mediated skin inflammation in mice and rats.

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/>