

News Release

December 20, 2022 Carna Biosciences, Inc.

Carna Announces Successful Development of New Tablet Formulation 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, announces the dosing of newly developed tablet formulation of AS-0871, an investigational small molecule drug designed to non-covalently inhibit Bruton's tyrosine kinase (BTK) with high selective profile targeting inflammatory and immune disorders in its Multiple Ascending Dose (MAD) study.

The phase 1 study of AS-0871, being conducted in the Netherlands, consists of Single Ascending Dose (SAD) study and MAD study in healthy volunteers. In the phase 1 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 phase 1 MAD study of AS-0871 was initiated in December 2021 and consists of two parts: BA part to evaluate the relative bioavailability of AS-0871 using new formulations and MAD part to evaluate the safety, tolerability, PK and PD of AS-0871 in multiple ascending dose study. The BA part evaluates relative bioavailability of multiple new formulations to select the best formulation. Following the BA part conducted using capsule formulation, the BA part using newly developed tablet formulation was initiated. The new tablet formulation showed excellent results superior to the capsule formulation in various studies including animal tests and expected to demonstrate the better bioavailability. The MAD part will be initiated after completing the analysis of the BA part.

We have started partnering activity to find a licensing or co-development partner who will conduct the Phase 2 study of AS-0871. We hope to accelerate the development of AS-0871 and contribute to the patients who need better treatment.

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-α, 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.

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