

News Release

December 29, 2021 Carna Biosciences, Inc.

Carna Announces Initiation of MAD study of Phase 1 Clinical Study for 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 initiation of phase 1 Multiple Ascending Dose (MAD) study 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, using a new drug formulation

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 consists of three parts: BA part to evaluate the relative bioavailability of AS-0871 using new formulations, MAD part to evaluate the safety, tolerability, PK and PD of AS-0871 in multiple ascending dose study, and SPT part to evaluate the effect of AS-0871 on allergen-induced skin reaction in the skin prick test (SPT) to assess the potential of AS-0871 for the treatment of Chronic Spontaneous Urticaria (CSU), a disease with high unmet needs.

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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