CARNA BIOSCIENCES

News Release

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Carna Biosciences, Inc.

Carna Announces Positive Results from the Phase 1 MAD study of Sofnobrutinib (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 positive results from the Phase 1 clinical trial in healthy volunteers evaluating multiple ascending doses (MAD) of sofnobrutinib (AS-0871), an investigational small molecule drug designed to non-covalently inhibit Bruton's tyrosine kinase (BTK) with high selective profile developing for the treatment of inflammatory and immune disorders.

The Phase 1 trial of sofnobrutinib in healthy volunteers consists of two studies, single ascending dose (SAD) study and MAD study, and the MAD study is designed as a two-part trial: bioavailability (BA) part and MAD part to evaluate the safety, tolerability, pharmacokinetic (PK) and pharmacodynamic (PD) of sofnobrutinib. Following the successful completion of the BA part, the MAD part was initiated in the Netherlands in January 2023 and the dosing of all dose levels planned was completed in April 2023. The Clinical Study Report of the MAD study has been finalized and the results from the MAD part include the following:

Summary of Results of sofnobrutinib

- Double blinded, placebo-controlled, randomized multiple ascending dose study in healthy volunteers.
- 14-day multiple oral doses of sofnobrutinib tablets in 3 cohorts (50, 150 or 300 mg twice daily)
- The safety, tolerability, PK and PD were evaluated.
- Well tolerated with no dose-limiting adverse events (AEs): AEs were mostly mild.
- Favorable safety profile up to 300 mg twice daily
- Favorable PK profile: approximately dose proportional with increasing doses
- Robust PD effect was observed: over 90% inhibition for basophils activation on Day 14 at 150 and 300 mg BID doses.

These results from the Phase 1 studies of sofnobrutinib support to advance sofnobrutinib into Phase 2 clinical development for further investigations.

"To develop sofnobrutinib in non-oncology fields, we believe its safety profile is the most important factors for success," said Kohichiro Yoshino, Ph.D., President and Chief Executive Officer of Carna Biosciences. "We are pleased that the results from this 2-week MAD study are promising for safety and tolerability of sofnobrutinib with the clinically meaningful pharmacodynamic effects. Based on these positive results, we will actively seek strategic partners to accelerate the patient studies of sofnobrutinib."

About sofnobrutinib (AS-0871)

Sofnobrutinib 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, sofnobrutinib 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 sofnobrutinib demonstrated the excellent therapeutic effects in a mouse model of collagen-induced arthritis. In addition, sofnobrutinib prevented IgE-mediated skin inflammation in mice and rats.
Sofnobrutinib 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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