Nimbus Therapeutics Presents Clinical Data from Phase 1b Study of Oral Allosteric TYK2 Inhibitor at AAD Annual Meeting

CAMBRIDGE, Mass. – March 25, 2022 – Nimbus Therapeutics, a clinical-stage company that designs and develops breakthrough medicines through its powerful computational drug discovery engine, today presented data from the Phase 1b clinical trial of its investigational oral allosteric tyrosine kinase 2 ("TYK2") inhibitor, NDI-034858, in patients with moderate-to-severe plaque psoriasis at the 2022 American Academy of Dermatology (AAD) Annual Meeting.

The study enrolled 26 patients with moderate-to-severe plaque psoriasis and was completed in April 2021. Patients received once-daily doses of either NDI-034858 (5mg, 10mg, or 30mg) or placebo over 28 days. As a Phase 1 study, the primary objective was evaluation of safety, and NDI-034858 was observed to be generally well tolerated. No serious adverse events were observed and no trends of adverse events were noted with increasing drug exposure. Most treatment-emergent adverse events were mild or moderate in severity.

Nimbus' data indicate that treatment with NDI-034858 resulted in improvement across multiple measures of disease pathology and normalization of molecular and inflammatory pathways dysregulated in psoriasis. Additionally, NDI-034858 showed a dose-dependent trend in exploratory clinical activity, measured by mean percent decrease in Psoriasis Area and Severity Index score at four weeks.

In patients treated with NDI-034858, investigators observed decreased thickness of lesional skin epidermis and decreased Ki67 expression (a marker of cell proliferation), as well as resolution of elevated keratin-16 expression. mRNA analyses of skin biopsies showed decreased expression of several psoriasis-related genes and up to 50% improvement in the expression of skin transcriptomes previously associated with psoriasis in lesional skin through microarray analysis. The poster, titled "Analysis of histologic, molecular and clinical improvement in moderate-to-severe psoriasis: Results from a Phase 1b trial of the novel allosteric TYK2 inhibitor NDI-034858," is on display through March 27, 2022.

"TYK2 plays a central role in both innate and adaptive immune responses and we believe is a promising target for treating a wide range of autoimmune and inflammatory diseases," said Bhaskar Srivastava, M.D., Ph.D., Vice President of Early Clinical Development at Nimbus. "We are pleased to see the advancement of our allosteric TYK2 inhibitor program, which we believe supports our further development of this candidate as a potential oral treatment option for patients with moderate-to-severe plaque psoriasis."

About Nimbus Therapeutics
Nimbus Therapeutics is a clinical-stage company that designs and develops breakthrough medicines through its powerful and comprehensive computational drug discovery engine. Nimbus' pipeline is comprised of multiple selective small molecule compounds targeting proteins that are known to be fundamental drivers of pathology in highly prevalent human diseases and have proven difficult for drug makers to tackle. Nimbus is headquartered in Cambridge, MA. To learn more about Nimbus, please visit www.nimbustx.com.

About the Nimbus TYK2 Program
TYK2 is an important signal-transducing kinase that mediates immune signaling and is important in both adaptive and innate immune cells. TYK2 inhibition is a potentially promising treatment approach for a wide range of autoimmune and inflammatory diseases due to the protein's central role in both the innate and adaptive immune responses.

Nimbus is conducting two clinical studies to evaluate its novel allosteric TYK2 inhibitor, including an ongoing moderate-to-severe plaque psoriasis (NCT04999839) study and the recently initiated active psoriatic arthritis (NCT05153148) study. The psoriatic arthritis Phase 2b trial is a randomized, multicenter, double-blind, placebo-controlled study that will evaluate three dose levels of the investigational therapy taken orally once per day. It is planned to enroll approximately 260 subjects, with a primary endpoint of proportion of subjects achieving at least an American College of Rheumatology 20 response at week 12. Additional trial details can be found by visiting ClinicalTrials.gov.

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