



## **Nimbus Therapeutics Announces Positive Topline Results for Phase 2b Clinical Trial of Allosteric TYK2 Inhibitor in Psoriasis**

- *Once-daily, oral dosing with NDI-034858 achieved statistical significance in the number of moderate-to-severe psoriasis patients achieving PASI-75 compared to placebo -*
- *Company has readied NDI-034858 for Phase 3 study, planned to begin in 2023 -*
- *Results support best-in-class potential of NDI-034858 among allosteric TYK2 inhibitors -*

**BOSTON, Mass. – November 30, 2022** – [Nimbus Therapeutics](#), a clinical-stage company that designs and develops breakthrough medicines through its powerful computational drug discovery engine, today announced positive topline results from a Phase 2b clinical trial evaluating the allosteric TYK2 inhibitor NDI-034858 in patients with moderate-to-severe plaque psoriasis. Data from the 259 patients dosed in the study showed that NDI-034858 achieved the study’s primary efficacy endpoint, with a statistically significant greater proportion of patients reaching PASI-75 (a 75% improvement in skin lesions as measured by the Psoriasis Area and Severity Index) compared to placebo at 12 weeks. Additional endpoints in the study were successfully achieved and the safety of NDI-034858 was consistent with other leading allosteric TYK2 inhibitors. The company plans to present data from this trial at an upcoming medical conference.

“We are pleased to report success from our Phase 2b psoriasis patient trial that supports NDI-034858’s best-in-class potential among the new class of allosteric TYK2 inhibitors. Additionally the consistent safety profile seen in this study reinforces TYK2 inhibitors as a differentiated non-JAK therapeutic class,” said Bhaskar Srivastava, M.D., Ph.D., Nimbus’ Senior Vice President of Clinical Development. “I’d like to thank the patients, our investigators and collaborators who made this study possible.”

In addition to psoriasis, Nimbus is evaluating NDI-034858 in an ongoing Phase 2b trial in active psoriatic arthritis and intends to launch Phase 3 studies in psoriasis, along with future trials in other autoimmune indications including inflammatory bowel disease (IBD) and lupus.

“The promising topline data from Nimbus’ Phase 2b study provide further evidence that the allosteric TYK2 inhibitor class can deliver effective and safe treatments for patients living with psoriasis,” said April Armstrong, M.D., MPH, clinical investigator in the Phase 2b study and Associate Dean and Professor of Dermatology at the University of Southern California. “I look forward to seeing how the exceptional clinical profile of NDI-034858 may continue benefiting psoriasis patients and the broader autoimmune disease community that potentially stand to benefit from such a differentiated therapy.”

“The success of Nimbus’ allosteric TYK2 inhibitor program demonstrates the company’s ability to discover, design and develop medicines through late-stage development. In addition to NDI-034858, we’re excited about the potential for our selective HPK1 inhibitor, currently being studied in a Phase 1/2 study, to provide an additional treatment option for patients with solid tumors,” said Nathalie Franchimont, M.D., Ph.D., Nimbus’ Chief Medical Officer.

### **Study Design**

This Phase 2b trial ([NCT04999839](#)) was designed to assess the efficacy, safety and tolerability of NDI-034858 in patients with moderate-to-severe plaque psoriasis. It was a randomized, multicenter, double-blind, placebo-controlled study that evaluated four dosages of NDI-034858 taken orally once per day. Its primary endpoint was the proportion of patients achieving PASI-75, meaning a 75% improvement in skin lesions as measured by the Psoriasis Area and Severity Index, at 12 weeks.

### **About NDI-034858**

NDI-034858 is an allosteric TYK2 inhibitor developed by Nimbus Therapeutics that is being evaluated for the treatment of multiple autoimmune diseases. In preclinical studies, NDI-034858 has demonstrated exceptional functional selectivity and wide therapeutic margins. In Phase 1 studies, NDI-034858 showed a good tolerability profile, a dose-dependent trend in exploratory clinical activity and a pharmacokinetic profile allowing for once-daily solid oral dosing. In addition to psoriasis, Nimbus is evaluating NDI-034858 in an ongoing Phase 2b trial in active psoriatic arthritis ([NCT05153148](#)).

### **About Nimbus Therapeutics**

Nimbus Therapeutics is a clinical-stage, structure-based drug discovery company developing novel small molecule medicines designed to act against well-validated but difficult-to-drug targets implicated in multiple human diseases. Nimbus combines leading-edge computational technologies with a tailored array of machine learning-based predictive modeling approaches. Nimbus’ pipeline includes clinical-stage programs targeting TYK2 and HPK1 ([NCT05128487](#)), as well as a diverse portfolio of preclinical programs focused on cancer, inflammatory and autoimmune disorders and metabolic diseases. Nimbus is headquartered in Boston, MA. To learn more about Nimbus, please visit [www.nimbustx.com](http://www.nimbustx.com).

### **Media Contact**

Chris Railey, (617) 834-0936  
Ten Bridge Communications  
[chris@tenbridgecommunications.com](mailto:chris@tenbridgecommunications.com)