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The NIMML Institute and NImmune Biopharma Announce Publication of Positive First-in-Human Data of NIM-1324, a Phase 2 Candidate for Systemic Lupus Erythematosus, in *Clinical and Translational Science*

First-in-human clinical trial of NIM-1324 met all primary and secondary endpoints
Daily oral NIM-1324 treatment confirmed as well-tolerated and safe with no dose-limiting toxicities
Oral treatment with NIM-1324 validated to engage LANCL2 in humans using a transcriptional signature in blood

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BLACKSBURG, Va.--(BUSINESS WIRE)--The NIMML Institute, ("NIMML"), a 501 (c)(3) nonprofit research institute dedicated to the discovery of novel precision medicines for infectious and autoimmune diseases, today announced publication of positive Phase 1 clinical results for NIM-1324, a first- and potentially best-in-class once-daily, oral, systemically distributed LANCL2 agonist therapeutic for the treatment of Systemic Lupus Erythematosus (SLE). The results, published in *Clinical and Translational Science*, the journal of the American Society for Clinical Pharmacology and Therapeutics, validate NIM-1324 and the LANCL2 pathway as a safe and well-tolerated novel mechanism of action with no dose-limiting toxicities.

As part of a precision medicine research collaboration with NIMML, NImmune Biopharma ("NImmune"), a Phase 3 inflammation and immunology (I&I) private biopharmaceutical company focused on the discovery and development of first-in-class and best-in-class biomarker-driven I&I therapeutics, leveraged NIMML's A.I.-powered TITAN-X A.I. Platform to identify NIM-1324 as a next-generation precision medicine. Developed as a LANCL2 agonist with improved pharmacokinetics, NIM-1324 is an investigational new drug for SLE, for which the current drugs have a wide array of side effects.

"This study provides exciting first-in-human data for NIM-1324, meeting all primary and secondary endpoints for safety and tolerability to enable further clinical trials in patients," said Dr. Josep Bassaganya-Riera, Founding Director of NIMML and NImmune Founder & CEO. "The latest clinical results continue the pattern observed with therapeutics targeting the LANCL2 pathway, which offer a safe and potentially best in class therapeutic effect in multiple I&I indications. The significant progress over the last 12 months by our team to advance the development of wholly-owned NIM-1324 highlights the efficiency of our business model and the TITAN-X A.I. Platform. Just like omilancor, our lead program in IBD currently in pivotal Phase 3 clinical development for ulcerative colitis, NIM-1324 offers urgently needed first-in-class precision medicines for I&I with a novel mechanism of action, no dose-limiting toxicities and the convenience of once daily oral dosing."

Study Design

To evaluate the safety of NIM-1324 in humans, the study tested single and multiple ascending doses of NIM-1324 in normal healthy volunteers in a blinded, placebo-controlled clinical design. As NIM-1324 is an investigational new therapy for autoimmune disease, particular notice was taken on the systemic hematological parameters after NIM-1324 dosing. The pharmacokinetics of NIM-1324 were assessed within blood to confirm systemic exposure of NIM-1324 in humans.

Among the results of the study, single or multiple oral dosing with NIM-1324 for up to 1500 mg/d did not produce severe adverse effects (AE) or increased total AE rates compared to placebo. No significant findings were observed by biochemistry, coagulation, hematology, or urinalysis relative to placebo. Additionally, dose-proportional change in plasma exposure within the therapeutic range was reported with no accumulation during the dosing period. Oral NIM-1324 upregulated expression of mitochondrial metabolism genes, while downregulating markers of phagocyte activation, in correlation with the whole blood transcriptomic signature generated in preclinical therapeutic efficacy programs. The safety and pharmacokinetic profile discovered were consistent with nonclinical findings, further supporting NIM-1324's continued clinical development.

About NIM-1324

NIM-1324 is an oral, systemically distributed, small-molecule therapeutic candidate which activates LANCL2, a surface membrane-associated receptor that is responsible for modulating key cellular and molecular changes tied to inflammatory and autoimmune diseases. By activating the LANCL2 pathway, NIM-1324 increases the anti-inflammatory capacity and stability of regulatory CD4+ T cells while also supporting the metabolic demands of autophagy in phagocytes. To date, treatment with NIM-1324 has reduced the production of interferon alpha in blood from systemic lupus erythematosus (SLE) patients and provided protection from clinical disease and tissue pathology in mouse models of lupus, rheumatoid arthritis, multiple sclerosis and other undisclosed I&I indications. Phase 2-ready NIM-1324 has successfully completed Phase 1 clinical testing where it met all endpoints and demonstrated a dose proportional change in plasma exposure within the therapeutic range with no accumulation.

About Systemic Lupus Erythematosus (SLE)

SLE is a chronic autoimmune disorder that causes systemic inflammation and organ damage. SLE can affect the skin, joints, blood vessels, kidneys, lungs, brain, and heart, resulting in fatigue, skin rashes or lesions, fevers, arthritis, lung, heart and kidney damage, seizures, and psychosis. SLE symptomatology often results in low quality of life, and 17% of SLE patients will need a kidney transplant. SLE affects over 1.5 million patients in the United States and over 5 million patients worldwide. With more than half of patients experiencing at least one flare per year or presenting persistently active disease, there is an unmet medical need in SLE for the development of safer and more effective therapeutics.

About the TITAN-X Platform

The TITAN-X Precision Medicine Platform combines A.I. methodologies, bioinformatics, and advanced computational modeling to accelerate the development of precision medicines to address the unmet clinical needs of patients with autoimmune diseases. Building upon NIMML's expertise in engineering large-scale computational models to study immunity as a massively and dynamically interacting system, the TITAN-X Platform integrates each step from new target discovery to enabling biomarker-driven precision clinical drug development. Following bioinformatic analysis of differentially expressed genes from patient biopsy specimens, the TITAN-X Platform can identify transcriptional predictive signatures by using its advanced A.I. algorithms. By analyzing gene expression patterns and integrating clinical data, the TITAN-X Platform can identify responder patterns, facilitating precision medicine approaches for drug development. This ensures that patients receive therapies that are most likely to benefit them according to their unique genetic signatures and clinical profiles, and that are tailored to maximize efficacy, safety, tolerability and minimize adverse side effects. The TITAN-X Platform has shaped the development of omilancor, NX-13 (acquired by Abbvie in March 2024 and now called ABBV-113), NIM-1324 and multiple additional novel MoA targets for I&I indications.

About NIMML

The NIMML Institute is a 501 (c)(3) non-profit foundation focused on applying transdisciplinary, team-science approaches to precision medicine. The NIMML Institute applies its TITAN-X advanced A.I.-powered platform to large-scale transdisciplinary projects aimed at solving important public health problems through precision medicine. NIMML combines the expertise of immunologists, computational biologists, toxicologists, computational modelers, translational and clinical researchers, and molecular biologists to translate novel scientific discoveries into medicines for human diseases. The Institute is headquartered in Blacksburg, VA. For more information, please visit www.nimml.org or contact pio@nimml.org.

About NImmune Biopharma

NImmune is a late-stage precision inflammation and immunology (I&I) biopharmaceutical company that develops novel best-in-class biomarker-driven immunoregulatory therapeutics. Underpinned by a discovery platform that utilizes advanced computational modeling, A.I. and bioinformatics coupled with biomedical research capabilities to pioneer innovation in immunoregulatory drug development, NImmune's business model enables the rapid and capital-efficient clinical development of high conviction drug candidates into New Drug Application (NDA) filing and commercialization. The lead product candidate from NImmune's discovery platform is omilancor, a wholly-owned oral, once-daily, gut-restricted, first-in-class therapeutic currently in Phase 3 development, which targets LANCL2 for Ulcerative Colitis and Crohn's disease. Phase 2 proof-of-concept data for omilancor show potential best in class efficacy and safety. For more information, please visit www.NIMMUNEBIO.COM or contact media@nimmunebio.com.

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