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NImmune Biopharma to Present at DDW'25 the First Ever Head-to-Head Clinical and Translational Results for Omilancor Versus Leading Anti-TL1A in IBD Showing Superiority and Complementarity

New results affirm omilancor's ability to safely reverse colonic regulatory T-cell (Treg) depletion and mitochondrial dysfunction in severe UC patients which defines a core subset of patients traditionally refractory to existing approved IBD treatments and highly responsive to omilancor

Activation of LANCL2 by omilancor in treating IBD outperforms anti-TL1A blockage with a superior safety profile and a once daily oral dosing

Two head-to-head studies highlight omilancor's best-in-class efficacy, unrivaled safety, and the complementarity of LANCL2 and anti-TL1A novel mechanisms of action in treating IBD

Results demonstrate omilancor's commercial path to UC patients, affirm ongoing plans to complete Phase 3 development of omilancor in UC and initiate the New Drug Application (NDA) to the U.S. FDA by 2027 with additional NDAs soon thereafter

Omilancor is a once-daily, oral, best- and first-in-class therapy in Phase 3 clinical development for UC, with multiple I&I indications in progress

Blacksburg, VA – May 6, 2025 – NImmune Biopharma ("NImmune"), a private late-stage precision inflammation and immunology ("I&I") biopharmaceutical company that develops novel best-in-class biomarker-driven immunoregulatory therapeutics for inflammatory and autoimmune diseases, will present at Digestive Disease Week 2025 first ever head-to-head clinical and translational results from two studies for omilancor, a Phase 3 first-in-class LANCL2 agonist versus the leading anti-TL1A candidate currently also in Phase 3 development for ulcerative colitis ("UC"). The new findings demonstrate that once daily oral omilancor is superior to the leading anti-TL1A antibody in efficacy with an unrivaled safety profile. In addition to the late-stage UC program, omilancor is currently in Phase 2 clinical development for Crohn's disease, with other inflammatory and autoimmune indications in progress.

The new findings demonstrate that oral omilancor treatment significantly ameliorated disease activity compared to anti-TL1A antibody and placebo. In addition, omilancor outperformed anti-TL1A antibodies against histological measures and in downregulating inflammatory genes implicated in the recruitment and activation of neutrophils, including Cxcl5, as well as genes typically associated with increased disease severity in inflammatory bowel disease ("IBD") and gut mucosal inflammation.

"We created omilancor to be a unique, best-in-class oral therapy that can break through the treatment ceiling in IBD. Hence, we are not surprised by omilancor's remarkable consistency across multiple clinical studies as a best-in-class efficacy with unrivaled safety with no dose-limiting toxicities," said Dr. Josep Bassaganya-Riera, Founder and CEO of NImmune Biopharma. "Omilancor's development leverages the TITAN-X A.I. Platform to provide a novel MoA that we are pleased has now been proven in multiple studies to outperform approved and in development IBD therapies, including anti-TL1A treatments."

As part of a precision medicine research collaboration with The NIMML Institute ("NIMML"), a research institute dedicated to combining advanced computational modeling using A.I. with translational research and clinical testing to accelerate the development of the next wave of precision medicines for inflammatory and autoimmune diseases, NImmune leveraged the A.I.-powered TITAN-X A.I. Precision Medicine Platform to analyze global transcriptomics datasets from colonic biopsies of UC patients and performed advanced computational simulations of the effects of LANCL2 and anti-TL1A in immunometabolism.

At Digestive Disease Week 2025, presented clinical research findings demonstrated that daily oral omilancor was effective in inducing clinical remission in 30.4% of active UC patients and in 33.3% of biologic refractory UC patients at the designated Phase 3 dose of 440 mg/day. New results showed that once-daily oral omilancor treatment reverses immunometabolic dysfunction present in severe UC patients and induces clinical remission, with a biomarker response detected in as little as two weeks after initiating treatment. Multiple clinical studies have now shown that omilancor is remarkably safe with no identifiable treatment-related adverse events. Omilancor treatment reverses the colonic regulatory T-cell (Treg) depletion and mitochondrial dysfunction in severe UC patients which defines a core subset of patients traditionally refractory to treatment options highly responsive to LANCL2 drugs.

Dr. Bassaganya-Riera added, “Despite a multitude of FDA-approved treatments and the emergence of combination treatments for UC and CD, there remains a significant unmet clinical need for novel treatments that can induce and maintain significant improvements in clinical remission and break the efficacy ceiling of current therapies. Omilancor has now shown it can be a safe and effective treatment for patients with the most severe cases that are resistant to current therapies. Its unrivaled safety, best-in-class efficacy and convenient once-daily oral dosing is the ideal profile of a backbone therapy in UC and multiple additional I&I indications. Mounting mechanistic, clinical and translational evidence has created a clear pathway to rapid commercialization, to completing Phase 3 clinical development, and to initiating regulatory filings in preparation for a commercial launch designed to meet the urgent needs from mild patients with active disease to the most severe and unresponsive cases refractory to currently approved IBD therapies.”

Digestive Disease Week 2025 Presentations

Oral Omilancor Treatment Outperforms Anti-TL1A Therapeutics in IBD [#0005]

- Monday, May 5, 9:00 a.m. PT

Omilancor Reverses Colonic Treg Depletion and Downregulation of Mitochondrial Metabolism in Severe Ulcerative Colitis Patients [#0024]

- Sunday, May 4, 12:30 p.m. PT

About NImmune Biopharma

NImmune is a private late-stage precision inflammation and immunology (“I&I”) biopharmaceutical company that leverages a proprietary A.I. platform to rapidly and capital efficiently develop novel best-in-class biomarker-driven immunoregulatory therapeutics. Underpinned by the TITAN-X computational platform that utilizes advanced A.I., advanced computational modeling, and bioinformatics and biomedical research capabilities to pioneer innovation in the development and commercialization of novel best-in-class immunoregulatory and immunometabolic therapies, NImmune’s business model enables the rapid and capital-efficient clinical development of high conviction drug candidates to New Drug Application (NDA) filing and commercialization. The lead product candidate from NImmune’s internal discovery platform is omilancor, a wholly owned Phase 3 oral, once-daily, gut-restricted, first-in-class therapeutic targeting LANCL2 for Ulcerative Colitis, with fast follower potential in Crohn’s disease, Psoriasis and other inflammatory and autoimmune diseases. Final and complete published Phase 2 first-in-patient data for omilancor in UC show best in class efficacy and safety. Additional information: www.NIMMUNEBIO.COM.

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 immunoregulatory therapeutics like omilancor, NX-13 (acquired by Abbvie in March 2024) and NIM-1324.

About NIMML

The NIMML Institute is a 501 (c) (3) non-profit foundation dedicated to combining advanced computational modeling using A.I. with translational research and clinical testing to accelerate development of the next wave of precision medicines for inflammatory and autoimmune diseases. 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. The Institute is headquartered in Blacksburg, VA. For more information, please visit www.NIMML.org.

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