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NImmune Biopharma Acquires Development and Commercialization Rights to Omilancor in Asian Markets

Transaction is highly shareholder value accretive, enabling the potential acceleration of the global registration directed Phase 3 program in ulcerative colitis, the Phase 2 program in Crohn's disease, and additional I&I indications

Global registration directed Phase 3 protocols in ulcerative colitis have regulatory approval in the U.S. and trials include clinical sites in the U.S., China, Australia, South Korea, Japan, Europe, Latin America and MENA regions

Published final and complete Phase 2 data position omilancor as best-in-class therapeutic for ulcerative colitis in a once-daily oral with unrivaled safety

Topline Phase 3 clinical results in ulcerative colitis patients are anticipated by end of 2026 and the first NDA filing in 2027

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BLACKSBURG, Va.--(BUSINESS WIRE)--NImmune Biopharma ("NImmune"), a private late-clinical-stage precision inflammation and immunology ("I&I") biopharmaceutical company developing novel biomarker-driven immunoregulatory therapeutics, today announced the acquisition of development and commercialization rights for omilancor in Asia. Covered markets include China, Macau, Hong Kong, Taiwan, Thailand, Singapore, South Korea, Cambodia, Indonesia, Myanmar, the Philippines, Thailand, and Vietnam. Upon closing of this transaction, NImmune will wholly own global rights to omilancor and the entire LANCL2 portfolio of immunoregulatory therapeutics. Omilancor is a once-daily, oral, best- and first-in-class therapy in Phase 3 clinical development for ulcerative colitis (UC) and Phase 2 for Crohn's disease (CD), with multiple I&I indications planned.

"The wind-down of LianBio, announced on February 13, 2024, provided an unprecedented opportunity to consolidate global rights to omilancor in NImmune and capture significant additional value for shareholders. We are very excited to continue late-stage development of omilancor and bring the best- and first-in-class potential of an oral therapeutic to patients with ulcerative colitis and Crohn's disease," said Dr. Josep Bassaganya-Riera, Founder & CEO of NImmune. "The timing of this transaction could not have been more ideal as we launch the global Phase 3 program of omilancor in UC. We now look forward to completing ongoing discussions with potential global and regional strategic partners that can help to further accelerate Phase 3 timelines and bring the best-in-class potential of omilancor to address the unmet needs of millions of IBD patients in the U.S. and worldwide."

By activating the LANCL2 pathway and modulating the interactions between immunological and metabolic signals in immune and epithelial cells, omilancor is designed to create a favorable regulatory microenvironment in the gut, decreasing the production of key inflammatory mediators such as TNF, increasing anti-inflammatory functions in regulatory T cells (Treg) and phagocytes within the site of inflammation while decreasing excessive or pathogenic effector immune responses such as Th1 and Th17. LANCL2 activation enhances the anti-inflammatory functions of Treg cells by amplifying IL-2 signaling and promoting metabolic reprogramming resulting in enhanced mitochondrial metabolism. Over 90% of downregulated genes in IBD are related to mitochondrial metabolism. Activation of LANCL2 with omilancor reverses this downregulation.

In a Phase 2 double-blind, randomized, placebo-controlled trial, oral once daily omilancor induced clinical remission in 30.4% of patients with active UC (78% w/ baseline MES of 3) or, a placebo-adjusted 26.7% (P = 0.01) with no identified treatment related adverse events. Ongoing development of a precision biomarker signature intended to serve as a companion diagnostic to omilancor may help to more precisely identify responders and maximize enduring clinical remission. Omilancor's predictive biomarkers were developed with the guidance of the NIMML Institute's TITAN-X platform, a proprietary advanced computational modeling and AI-powered precision medicine discovery engine that efficiently accelerates biomarker-driven I&I therapeutic development.

About NImmune Biopharma

NImmune is a late-stage precision immunology 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 clinical development, which targets LANCL2 for ulcerative colitis and Crohn's disease. Published, final and complete 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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