ILIAS Biologics Publishes Phase 1 Clinical Trial Results of ILB-202 in JEV

First-in-human study of a systemically administered anti-inflammatory engineered exosome therapy highlights its clinical potential and commercial viability

ILIAS Biologics Inc. Laboratory (Image: ILIAS Biologics Inc.)

CEO Dr. Chulhee Choi (Image: ILIAS Biologics Inc.)

SEOUL, EUNPYEONG, SOUTH KOREA, September 29, 2025 / EINPresswire.com/ -- ILIAS Biologics Inc. (ILIAS, CEO: Dr. Chulhee Choi), a biotech company pioneering precision therapeutics based on engineered exosomes, announced that the results of its global Phase 1 clinical trial for its lead candidate, ILB-202, have been published in the September 2025 issue of the Journal of Extracellular Vesicles (JEV), the official journal of the International Society for Extracellular Vesicles (ISEV).

JEV is a leading peer-reviewed journal indexed in the Science Citation Index (SCI), with an impact factor of 16. The publication of this study not only validates the scientific and medical relevance of ILB-202 but also underscores its global competitiveness and commercial potential in the rapidly growing field of exosome-based therapeutics.

The article, titled “Safety and Anti-Inflammatory Effects of Engineered Extracellular Vesicles (ILB-202) for NF-κB Inhibition: A Double-Blind, Randomized, Placebo-Controlled Phase 1 Trial” presents comprehensive data on the safety, tolerability, and exploratory pharmacodynamic

properties of ILB-202 when administered intravenously to healthy volunteers.

The randomized, double-blind, placebo-controlled trial confirmed that ILB-202 was safe and well tolerated at all tested dose levels. Most notably, this study marks the world's first clinical demonstration of a systemically administered engineered exosome that selectively modulates pathological inflammation without inducing broad immunosuppression—signaling a paradigm shift in the treatment of immune-related diseases.

ILIAS Biologics Inc. Headquarters (Image: ILIAS Biologics Inc.)

Through single-cell RNA sequencing of peripheral blood samples collected before and after drug administration, the study demonstrated that ILB-202 primarily targets subsets of monocytes and selectively downregulates NF-κB, a key driver of inflammatory signaling. Concurrently, it activates anti-inflammatory pathways, such as those involving TGF-β and visfatin, promoting a return to immune homeostasis.

Unlike conventional NF-κB inhibitors, which frequently suppress normal immune function and pose safety concerns, ILB-202 preserves physiological immunity while precisely targeting pathologically overactivated inflammation. This differentiated mechanism underscores its potential as a next-generation immunomodulatory agent.

This trial represents the first-in-human application of ILB-202, developed using ILIAS's proprietary exosome engineering platform, EXPLOR®. It is also the first trial globally to demonstrate both the safety and pharmacodynamic activity of a systemically administered engineered exosome. This milestone significantly broadens the industrial and clinical potential of exosome-based therapeutics—not only as standalone treatments but also as scalable platform drugs. Strategic applications are anticipated in high unmet-need areas such as autoimmune and rare inflammatory diseases.

The trial was conducted in collaboration with Professor Heon Yung Gee of the Department of Pharmacology at Yonsei University College of Medicine. It was supported by the Ministry of Health and Welfare of Korea through the Korea Health Industry Development Institute (KHIDI), under the Advanced Biomedical Technology Development Program.

Dr. Chulhee Choi, CEO of ILIAS, stated, "ILB-202 is a next-generation immunomodulatory exosome therapy with broad potential across systemic inflammatory diseases. This publication

in JEV marks a pivotal milestone, validating the scientific rationale and clinical feasibility of our platform. We are committed to accelerating global development and expanding into additional indications through strategic collaborations and licensing partnerships."

Meanwhile, ILIAS is currently advancing protocol development and regulatory discussions to initiate the next phase of clinical trials for ILB-202. In parallel, the company is accelerating the industrialization and commercialization of next-generation exosome therapeutics by expanding its pipeline across multiple immunology and inflammatory disease indications using its proprietary exosome platform.

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