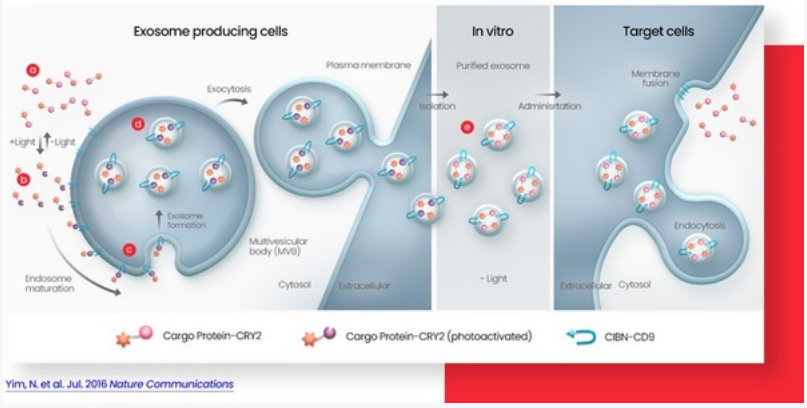
ILIAS Biologics Secured Phase 1 Results for Exosome Therapeutic and Published Research Results in International Journal

Expected to demonstrate higher safety compared to existing anti-inflammatory treatments, signaling a strong entry into the global market

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



EXPLOR® platform technology (Image: ILIAS Biologics Inc.)

EUNPYEONG-GU, SEOUL, KOREA, July 23, 2024 /EINPresswire.com/ -- ILIAS Biologics Inc. (CEO Chulhee Choi, hereinafter referred to as ILIAS), a biotech of exosome therapeutics, has taken a step closer to global technology transfer by securing the clinical study report for their exosome-based anti-inflammatory therapeutic from a clinical trial in Australia.

ILIAS recently announced that they have received the final clinical study report (CSR) for their lead pipeline exosome therapeutic, 'ILB-202,' from a Phase 1 clinical trial completed in Australia in November last year.

'ILB-202' is an exosome therapeutic candidate that carries the anti-inflammatory protein srIκB (super-repressor IκB), which inhibits the activity of NF-κB, a pivotal cellular protein that activates inflammation. The srIκB protein prevents NF-κB from entering the cell nucleus and functioning, thereby suppressing the inflammatory response. 'ILB-202' utilizes ILIAS's proprietary 'EXPLOR®' platform technology to load high-molecular-weight pharmacological biologics into the exosomes.

According to ILIAS, this trial, conducted from April to November 2023 in Australia with 18 adult participants, is the world's first systemic administration clinical trial for engineered exosome therapeutics. The trial, involving three cohorts of low, medium, and high doses, was a randomized, placebo-controlled, double-blind study to evaluate the safety and tolerability of a single intravenous (i.v.) infusion of 'ILB-202' in healthy adults.


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

As a result, all 18 participants completed the trial without any dropouts, and no dose-limiting toxicity (DLT) or serious adverse events (SAEs), including death, were observed at any dose level. Additionally, no infusion-related reactions or cytokine storms were reported, confirming the safety of 'ILB-202.'

ILIAS explained that the comprehensive analysis of the safety and tolerability data of 'ILB-202' confirmed through this CSR indicates a higher expected safety compared to existing anti-inflammatory treatments. Moreover, the trial was designed not only to evaluate safety and tolerability but also to explore efficacy. ILIAS anticipates that the exploratory efficacy evaluation results from analyzing participants' blood samples will demonstrate the utility of their platform technology.

Meanwhile, ILIAS announced that their non-clinical research results for the clinical application of engineered exosomes designed to deliver therapeutic proteins into cells were published in the June online edition of the prestigious international journal 'Stem Cells Translational Medicine.' This review paper summarized (1) research results validating the monocyte and NF-κB gene reduction effects of 'ILB-202' and the importance of single-cell RNA sequencing analysis, (2) various exosome engineering strategies for active targeting, and (3) the potential therapeutic applications of engineered exosomes in treating other diseases, such as CNS disorders and cancers.

The ILIAS research team views this study as "an example demonstrating the importance of pharmacological validation through single-cell RNA sequencing analysis in non-clinical and clinical research on engineered exosome therapeutics and strong evidence of 'ILB-202's targeted delivery capability and effective target binding." Additionally, they expect that engineered

exosomes will maximize drug efficacy while minimizing adverse effects by selectively delivering drugs to target organs or tissues of interest by systemic administration.

ILIAS' CEO Chulhee Choi stated, "Many global big pharma companies with whom we have been discussing technology transfer have wanted to confirm the safety and potential therapeutic efficacy of the engineered exosomes through systemic administration in humans. Based on these clinical trial results, we expect discussions on technology licensing to progress more rapidly, and next-generation targeted exosome technology will be recognized for its potential to bring groundbreaking changes in the treatment of various intractable diseases."

Founded in 2015, ILIAS has been developing its own pipeline focusing on inflammatory, immune, and renal diseases based on its unique EXPLOR® platform technology, which enables the loading of macromolecules into the exosomes. In this process, they have established Exo-Target®, a technology for active tissue targeting through the design and manipulation of the exosome surface, and Pure-Exo®, a technology for the scalable production of high-purity exosome therapeutics.

ILIAS has been actively pursuing global commercialization efforts, being selected for global expansion support projects this year. They have also been recognized for their R&D capabilities and innovation by being granted funds for national drug development and drug delivery system development projects supported by the Korean government.

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