Immunity Pharma

07.04.2025 – 09:00 Uhr

Immunity Pharma Presents New Data Supporting the Efficacy of IPL344 in ALS

Jerusalem (ots/PRNewswire) -

- Results from phase 2a trial in ALS patients were published in Muscle and Nerve.
- Statistically significant 58% to 64% slower ALSFRS-R progression rate in IPL344-treated patients compared to the matched PRO-ACT records.
- NfL was reduced by 27% for patients treated for at least two months.
- Unadjusted median survival for participants in the IPL344 group was 43.4 months compared with 19.1 months in the historical control group.
- IPL344 was safe and well-tolerated.

The results of a phase-2a clinical trial of IPL344 were published in *Muscle and Nerve*, the leading American scientific journal specializing in ALS and neuromuscular diseases.

Slower ALSFRS-R Progression Following Treatment

The nine study participants were treated for varying durations, averaging 11 months per participant, including one individual treated under a compassionate use protocol with comparable dose ranges. Multiple statistical methods were applied to assess the results of this study, primarily through comparison with PRO-ACT, the largest ALS clinical trials dataset available.

ALSFRS-R progression rate was reduced by 58% (median, P=0.04) between each participant and their individually matched PRO-ACT control group (116 participants in a group on average). Adjustment for disease stage and rate-indicating covariates indicated a 64% slower ALSFRS-R progression (p = 0.034). All participants except one—who was treated for less than two months—exhibited slower disease progression than their matched controls, with 7 of the 9 progressing at least 40% slower.

NfL Reduction and Survival

Neurofilaments light chain (NfL), a biomarker for neuronal damage with increasing prominence in the evaluation of ALS studies, was measured before and after treatment. Six participants had blood sampling past the initial 28-day dose-escalating study. In these participants, plasma NfL concentrations were reduced from an average of 79.7 pg/mL at baseline to 58.6 pg/mL following treatment; a mean reduction of 27%.

Unadjusted median [95% CI] survival for participants in the IPL344 group, including follow-up beyond treatment period, was 43.4 months [20.5, NA] compared with 19.1 months [17.4, 23] in a historical control group (the placebo group of the ceftriaxone study, selected as control for its particularly long duration).

Additional Treatment Benefits

IPL344 treated participants gained weight (+0.47 kg/month), while those in the historical PRO-ACT placebo control lost weight (−0.39 kg/month); the difference was statistically significant (p = 0.02) when corrected for covariates.

With respect to the respiratory function, measured by slow vital capacity (SVC) adjusted for covariates, IPL344 treated participants had an adjusted mean change of −1.6% per month compared to −2.8% per month in the historical placebo, which is 44% slower.

The preliminary data indicate that IPL344 was safe and well-tolerated.

"There is a pressing need for therapies that can slow the progression of ALS beyond current options. The results observed in this open-label, small trial with IPL344 are good pilot data to inform design of next clinical trial, I do believe there are both scientific rationale and data to support going to a larger, randomized placebo- controlled trial." said Prof. Merit Cudkowicz, Executive Director, Mass General Brigham Neuroscience Institute, Massachusetts Boston.

"I am pleased to share this publication with the broader community. The study participants were specifically selected for their rapid disease progression, and these initial results are encouraging. I am looking forward to seeing this drug evaluated in a larger clinical trial."" said Prof. Marc Gotkine, Principal Investigator of the study and Head of Neuromuscular and EMG Unit at Hadassah Medical Center, Jerusalem.

"Despite the small size of study, we were able to demonstrate clinically meaningful improvements in the 5 endpoints assessed. We are encouraged by the magnitude and the consistency of the results. We thank Prof. Schoenfeld of Harvard medical school, for developing the statistical methods and performing the statistical analysis for this study. We also thank Prof. Shefner, the cofounder of NEALS and Prof, Cudkowicz for supporting our study design and evaluation" said Dr. Ilana Cohen, VP of R&D, Immunity Pharma.

"We thank the study participants and their families for their partnership and support. We are encouraged by the potential of IPL344 to be transformative in the fight against ALS, given its initial efficacy across multiple clinical endpoints. This efficacy is driven by its unique mechanism of action that targets key biological processes underlying ALS. We are currently preparing for a

large, placebo-controlled clinical trial to further evaluate IPL344 efficacy. If the current results will be reproduced in the larger study, they could offer meaningful benefits to individuals living with ALS." said Eran Ovadia, Immunity Pharma's CEO.

Paper details: Marc Gotkine, David A. Schoenfeld, Ilana Cohen, Jeremy M. Shefner, Yossef Lerner, Irun R. Cohen, Colin Klein, Eran Ovadia and Merit E. Cudkowicz, "Akt Activation with IPL344 Treatment for Amyotrophic Lateral Sclerosis: First in Human, Open-Label Study". *Muscle and Nerve*. 19 March 2025. **https://doi.org/10.1002/mus.28393**

About the Phase 1/2a ALS Clinical Trial

The Phase 1/2a trial is an open-label, dose-ranging study with once-daily IPL344 IV treatment (at home) for up to 3 years. The study includes a 28-day Phase 1 portion, followed by the Phase 2a portion of the study. The study was conducted at the Hadassah Medical Center, Jerusalem. All participants were rapidly progressing ALS patients.

About IPL344

IPL344 is Immunity Pharma's lead drug candidate. IPL344 was discovered in the Weizmann institute of Science, Israel, at Prof. Irun Cohen's Laboratory. IPL344 is being developed as an intravenous injection for the treatment of ALS.

IPL344 received orphan drug designation from FDA and EMA which grants exclusivity for at least seven years.

About Immunity Pharma

Immunity Pharma Ltd. (IPL) is a privately-held clinical-stage neurology-focused biopharmaceutical company that develops therapies for neurodegenerative diseases, with an initial focus on ALS. IPL's drugs are small biologically active peptides that stimulate therapeutic cell-signalling processes including activation of the Akt pathway which is down-regulated in neurodegenerative diseases. These drugs mitigate progression of neurodegenerative diseases by inducing survival-supporting processes and mitigating stress conditions. IPL's drugs are being developed as treatment for ALS, Parkinson's disease and other neurodegenerative diseases.

For more information, please visit www.immunitypharma.com

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