PhotoPharmics Announces Publication of Phase 2 Clinical Trial Results in Neurotherapeutics

Peer-reviewed Phase 2 Results Inform Ongoing Phase 3/Pivotal Trial of Celeste® in Parkinson's Disease

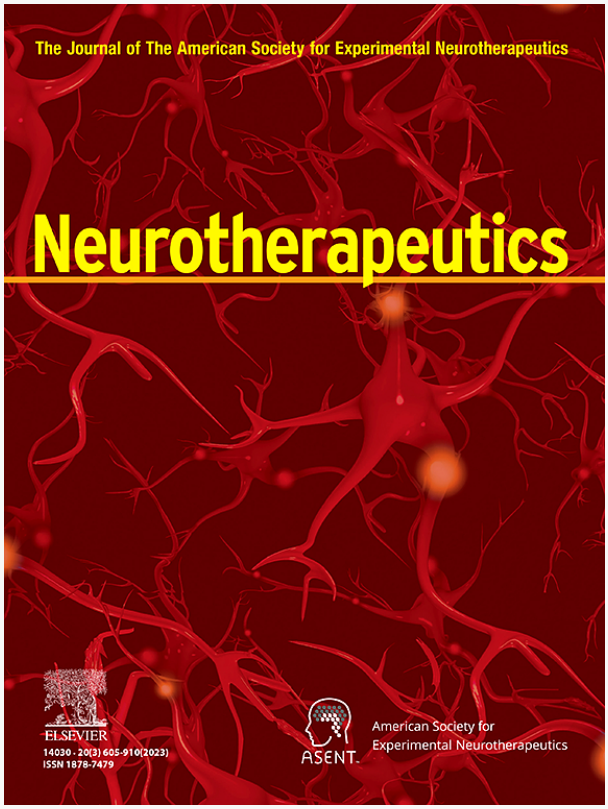
SALT LAKE CITY, UT, UNITED STATES, January 20, 2026 /EINPresswire.com/ -- PhotoPharmics, Inc. today announced the peer-reviewed publication of results from its Phase 2 randomized, double-blind, controlled clinical trial evaluating Celeste®, an investigational photo-neuromodulation device, in people living with Parkinson's disease (PD). The study has been published in the journal Neurotherapeutics. Celeste® has been designated by the U.S. Food and Drug Administration as a Breakthrough Device.

> "The Phase 2 study results provided critical learning that helped refine the design and powering of our Phase 3/Pivotal trial."
> *Dan Adams, Science Officer*

The publication marks an important scientific milestone for the Company and contributes to the growing body of clinical evidence examining circadian-effective photo-neuromodulation in PD. The Phase 2 findings informed the design of the Company's ongoing Phase 3/Pivotal trial, which is fully enrolled and expected to complete in Q2 2026.

The Phase 2 study evaluated daily photo-neuromodulation delivered via a patented spectral band of light frequencies designed to engage circadian pathways. The trial assessed both motor and non-motor features in individuals with PD receiving standard-of-care therapies. Celeste was well tolerated over the six-month period, with no serious adverse events reported.

The study's primary endpoint, change in the Movement Disorder Society–Unified Parkinson's Disease Rating Scale (MDS-UPDRS) total score, did not reach statistical significance ($p = 0.074$). The results nevertheless showed an 8-point between-group difference on the primary endpoint at six months, along with nominal statistical significance on selected secondary measures, including the Parkinson's Disease Questionnaire-39 (PDQ-39) quality-of-life measure (5.7 points, $p=0.038$) and the MDS-UPDRS Parts I+II (4.0 points, $p=0.037$). These findings informed the decision to advance the program into a Phase 3/Pivotal trial.



“The Phase 2 study results provided critical learning that helped refine the design and powering of our Phase 3/Pivotal trial,” said Dan Adams, Chief Science Officer of PhotoPharmics. “That translational step is exactly what this stage of development is intended to accomplish.”

As noted by the study authors, daily photo-neuromodulation was well tolerated by participants, with no serious adverse effects reported, and the findings support further investigation in larger, double-blind studies. The full article is available via Neurotherapeutics at: (https://www.sciencedirect.com/science/article/pii/S1878747925002065).

“This peer-reviewed publication reflects our commitment to scientific rigor and transparent reporting,” said Kent Savage, Chief Executive Officer of PhotoPharmics. “The Phase 2 data provided a critical learning step for the program and directly informed the design of our Phase 3/Pivotal trial, expected to complete in Q2 2026.”

Phase 3 Trial Update

Building on insights from the Phase 2 trial, PhotoPharmics completed enrollment in October 2025 for its Phase 3/Pivotal trial evaluating Celeste®, an investigational photo-neuromodulation device, in people living with Parkinson’s disease. The trial is advancing according to protocol, with anticipated data collection through April 2026 and is designed to further evaluate long-term safety and clinical outcomes aligned with regulatory expectations.

Savage added, “Full enrollment in our Phase 3 trial reflects the strong engagement of the Parkinson’s disease community and our clinical partners. We look forward to sharing trial results when the trial concludes.”

About PhotoPharmics

PhotoPharmics is a privately held, clinical-stage medical device company advancing investigational technologies for neurodegenerative disorders. The Company is developing Celeste®, an investigational photo-neuromodulation device designated by the U.S. Food and Drug Administration as a Breakthrough Device, which is currently being studied in clinical trials involving people living with Parkinson’s disease.

PhotoPharmics' clinical program includes a peer-reviewed Phase 2 randomized, controlled clinical trial and an ongoing Phase 3/Pivotal clinical trial expected to complete in Q2 2026. The Company's approach is grounded in decades of circadian biology research and translational science.

The Company's founders bring more than 30 years of experience in circadian and light-based therapies and previously developed specialized light solutions widely used for seasonal affective disorder and sleep disorders, which were acquired by Philips-Respironics in 2007.

PhotoPharmics is committed to delivering safe and rigorously evaluated solutions that address unmet needs in neurodegenerative disease. Learn more at www.photopharmics.com.

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Important Disclaimer

Celeste® is an investigational device and has not been authorized for marketing by the U.S. Food and Drug Administration.

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Forward-Looking Statements

This press release contains forward-looking statements, including but not limited to statements regarding the design, conduct, timing, and expected results of PhotoPharmics' clinical trials, including the ongoing Phase 3/Pivotal trial; future regulatory interactions; and continued clinical development activities. These statements are based on current expectations and assumptions and are subject to risks and uncertainties that could cause actual results to differ materially from those described. PhotoPharmics undertakes no obligation to update or revise any forward-looking statements, except as required by law.

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