BrainStorm Cell Therapeutics Announces Publication Calling for Updated FDA Approaches to ALS, Rare Diseases and Regenerative Medicine

Former FDA Associate Commissioner Peter Pitts and BrainStorm's Chaim Lebovits argue that regulation must keep pace with advances in biomarkers, AI, cell therapy and precision medicine

NEW YORK, June 2, 2026 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (OTCQB: BCLI) today announced the publication of an article examining how regulatory frameworks that govern ALS, rare diseases, and regenerative medicine can better keep pace with rapidly advancing science.

As the ALS community marks Lou Gehrig Day and reflects on the courage and resilience of those living with the disease, the publication highlights the growing need for regulatory approaches that keep pace with advances in science and the urgent realities faced by patients and families.

The article, *"Restoring Regulatory Fairness and Reclaiming Biomedical Leadership: ALS, Rare Disease Regulation, and the Future of Regenerative Medicine,"* was published in the *Journal of the Academy of Public Health* and co-authored by BrainStorm Board Member Peter J. Pitts, a former FDA Associate Commissioner, and BrainStorm President and CEO Chaim Lebovits.

The authors argue that advances in biomarkers, genomics, artificial intelligence, regenerative medicine and precision therapeutics are changing what is possible in drug development, while many regulatory approaches are reliant on older models of evidence generation. Amyotrophic lateral sclerosis (ALS) is used as a case study for a broader question: whether patients with serious, fast-moving diseases can benefit from modern science if regulatory tools do not evolve alongside it.

"We're asking regulators to evaluate 21st-century science with the most up to date tools," said Mr. Pitts. "The Agency now has these tools, including Accelerated Approval, adaptive trial design, Bayesian statistics, and biomarker qualification. In this paper we discuss how those tools can be applied more consistently in ALS and regenerative medicine."

The article examines how tools such as validated biomarkers, surrogate endpoints, adaptive trial designs, Bayesian statistics and earlier sponsor-regulator alignment can help improve the development of therapies for ALS and other rare diseases. These approaches, the authors write, may be especially important in diseases where patient populations are small, symptoms vary widely, and traditional clinical endpoints can take years to measure.

"When science advances, the system has to advance with it," said Lebovits. "Our Special Protocol Assessment, the first ever granted in ALS, is a good example of what is possible when a sponsor and regulator work together in good faith."

About BrainStorm Cell Therapeutics Inc.

BrainStorm Cell Therapeutics Inc. (OTCQB: BCLI) is a leading developer of autologous adult stem cell therapies for debilitating neurodegenerative diseases. The company's proprietary NurOwn® platform uses autologous mesenchymal stem cells to produce neurotrophic factor-secreting cells, designed to deliver targeted biological signals that modulate neuroinflammation and promote neuroprotection.

NurOwn® is BrainStorm's lead investigational therapy for amyotrophic lateral sclerosis and has received Orphan Drug designation from both the U.S. Food and Drug Administration and the European Medicines Agency. A Phase 3 trial in ALS has been completed, and a Phase 3b trial is set to launch under a Special Protocol Assessment agreement with the FDA — the first SPA ever granted for an ALS therapeutic candidate. To learn more, visit www.brainstorm-cell.com.

Notice Regarding Forward-Looking Statements

This press release contains forward-looking statements that are subject to substantial risks and uncertainties, including statements regarding meetings with the U.S. Food and Drug Administration, the Special Protocol Assessment, the clinical development of NurOwn® as a therapy for ALS, the future availability of NurOwn® to patients, and the future success of BrainStorm Cell Therapeutics. All statements, other than statements of historical fact, are forward-looking statements. Forward-looking statements are based on BrainStorm's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Readers should not place undue reliance on forward-looking statements. BrainStorm does not assume any obligation to update forward-looking statements except as required by law.

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