BrainStorm Cell Therapeutics Appoints Former FDA Associate Commissioner Peter J. Pitts to Board of Directors

Former Senior FDA Official Joins Board as Company Prepares to Initiate Historic Phase 3b ALS Trial Under Special Protocol Assessment

NEW YORK, May 28, 2026 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (OTCQB: BCLI), a leading developer of autologous stem cell therapies for neurodegenerative diseases, today announced that Peter J. Pitts has been appointed to the Company's Board of Directors, effective immediately.

Mr. Pitts is a globally recognized expert in healthcare policy, regulatory science, and U.S. Food and Drug Administration (FDA) governance. He previously served as Associate Commissioner at the FDA and as a member of the U.S. Senior Executive Service. His appointment comes as BrainStorm prepares to, upon acquisition of necessary funding, initiate its Phase 3b ENDURANCE trial evaluating NurOwn® for ALS under a recently executed FDA Special Protocol Assessment (SPA), the first SPA ever granted for an ALS therapeutic candidate.

"BrainStorm is conducting some of the most important and scientifically rigorous work in neurodegenerative medicine today," said Pitts. "The FDA's Special Protocol Assessment for this Phase 3b trial is unprecedented in ALS and sends a powerful signal that the agency recognizes both the seriousness of the disease and the strength of the trial design."

"Just as importantly, the FDA is now under new management - and we believe that creates a far greater opportunity for smart regulatory innovation, serious scientific engagement, and patient-focused flexibility than we've seen in recent years. Patients with terminal ALS do not have the luxury of bureaucratic drift or ideological grandstanding. They need urgency, rigor, and leadership."

"For too long, portions of the FDA confused caution with paralysis. With new leadership now in place, there is renewed opportunity for regulatory creativity grounded in science rather than institutional defensiveness. ALS patients cannot afford performative skepticism from regulators sitting comfortably outside the blast radius of this disease."

"I look forward to working with Chaim Lebovits, the Board, and leading ALS centers around the country to help ensure that sound science, regulatory common sense, and a relentless focus on patients bring this promising therapy across the finish line."

Chaim Lebovits, President and Chief Executive Officer of BrainStorm, added, "We are honored to welcome Peter Pitts to the BrainStorm Board at this defining moment for our Company and for the ALS community. Peter's unparalleled regulatory expertise, credibility, and commitment to patients will be invaluable as we initiate the Phase 3b ENDURANCE trial under our Special Protocol Assessment granted by the FDA."

Mr. Pitts currently serves as President and co-founder of the Center for Medicine in the Public Interest (CMPI). His commentaries on regulatory science and healthcare reform have appeared in *The Wall Street Journal*, *The New York Times*, and *The Washington Post*, and his peer-reviewed work has been published in leading journals including*The Lancet*, *JAMA*, and *NEJM Catalyst*.

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 (MSCs) to produce neurotrophic factor-secreting cells (MSC-NTF cells), designed to deliver targeted biological signals that modulate neuroinflammation and promote neuroprotection.
NurOwn® is BrainStorm's lead investigational therapy for amyotrophic lateral sclerosis (ALS) and has received Orphan Drug designation from both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). A Phase 3 trial in ALS (NCT03280056) has been completed, and a second Phase 3b trial is set to launch under a Special Protocol Assessment (SPA) agreement with the FDA. The NurOwn clinical program has generated valuable insights into ALS disease biology, including pharmacogenomic response associated with the UNC13A genotype, biomarker data collected at seven longitudinal time points, and a comprehensive analysis of the "Floor Effect" - a critical challenge in measuring clinical outcomes in advanced ALS. BrainStorm has published its findings in multiple peer-reviewed journals. In addition to ALS, BrainStorm has completed a Phase 2 open-label multicenter trial (NCT03799718) of MSC-NTF cells in progressive multiple sclerosis (MS), supported by a grant from the National MS Society. BrainStorm is also advancing a proprietary, allogeneic exosome-based platform designed to deliver therapeutic proteins and nucleic acids. The company recently received a Notice of Allowance from the U.S. Patent and Trademark Office for a foundational patent covering its exosome technology, further strengthening BrainStorm's growing IP portfolio in this emerging area of regenerative medicine. 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 (FDA), Special Protocol Assessment (SPA), the clinical development of NurOwn as a therapy for the treatment of ALS, the future availability of NurOwn to patients, and the future success of BrainStorm. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will" "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on BrainStorm's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. These potential risks and uncertainties include, without limitation, management's ability to successfully achieve its goals, BrainStorm's ability to raise additional capital, BrainStorm's ability to continue as a going concern, prospects for future regulatory approval of NurOwn, whether BrainStorm's future interactions with the FDA will have productive outcomes, and other factors detailed in BrainStorm's annual report on Form 10-K and quarterly reports on Form 10-Q available at http://www.sec.gov. These factors should be considered carefully, and readers should not place undue reliance on BrainStorm's forward-looking statements. The forward-looking statements contained in this press release are based on the beliefs, expectations, and opinions of management as of the date of this press release. We do not assume any obligation to update forward-looking statements to reflect actual results or assumptions if circumstances or management's beliefs, expectations or opinions should change, unless otherwise required by law. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements.

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