Stoke Therapeutics Announces CEO Transition

March 18, 2025

Edward M. Kaye, M.D., to Step Down as Chief Executive Officer

Director Ian F. Smith Appointed Interim Chief Executive Officer

Arthur Tzianabos Appointed Interim Executive Chairman of the Board

Board of Directors Initiates Search for Permanent Chief Executive Officer

BEDFORD, Mass.--(BUSINESS WIRE)--Mar. 18, 2025-- Stoke Therapeutics, Inc. (Nasdaq: STOK) is a biotechnology company dedicated to restoring protein expression by harnessing the body's potential with RNA medicine and has a lead investigational medicine, zorevunersen, in development as a first-in-class potential disease-modifying treatment for Dravet syndrome.

Today the Company announced that Edward M. Kaye, M.D., has decided to step down from his role as Chief Executive Officer effective as of March 19, 2025. To facilitate a smooth transition, Dr. Kaye will serve as an advisor to the Company and will continue to serve as a Director on Stoke's Board. Effective March 19, 2025, Ian F. Smith has been appointed Interim Chief Executive Officer. The current Chairman of the Board Arthur Tzianabos, Ph.D., has been appointed Interim Executive Chairman. He will support Mr. Smith and Dr. Kaye through the transition and lead the search for a permanent Chief Executive Officer.

Dr. Tzianabos said, "On behalf of the Board, I would like to thank Ed for his invaluable contributions to Stoke over the last seven years. Ed's vision and experience were instrumental in translating Stoke's science into a first-in-class potential disease-modifying medicine for Dravet syndrome. Ed successfully led the Company from a startup through many key development milestones, creating a strong foundation for continued success and future growth as we enter late-stage clinical development and prepare for commercialization. We look forward to continuing to benefit from Ed's expertise as a board member and advisor."

Dr. Tzianabos continued, "We are pleased to have Ian step in as Interim CEO to lead Stoke while the Board conducts its search for a permanent CEO. Ian's experience leading teams, developing and commercializing medicines for rare pediatric diseases, and time spent working with the Stoke team as an advisor and director over the past two years will provide continuity and will support continued advancement of our strategic and growth initiatives."

Dr. Kaye said, "It has been a privilege leading and working with the exceptionally talented team at Stoke. Our recent progress with zorevunersen including FDA Breakthrough Therapy Designation, positive data to support the potential for disease modification, global Phase 3 alignment and the partnership with Biogen, along with a capable leadership team, have established a strong foundation for Stoke's next chapter. I look forward to continuing to work with the team as a director and advisor to expand the platform to additional disease areas."

"I have great admiration for what the team has accomplished under Ed's leadership and look forward to working even more closely with them to continue the strong momentum underway at the company," said Mr. Smith. "Having been involved for most of my career in delivering life-changing medicines to patients with rare diseases, I am deeply committed to Stoke's mission and to advancing zorevunersen as a disease-modifying medicine for the treatment of Dravet syndrome. I also see significant future potential for the company's highly-differentiated platform to address other severe genetic diseases."

Ian F. Smith Biography

Ian F. Smith is a biotechnology leader with more than 20 years of finance and operations experience and extensive relationships in the industry. He has served as a member of Stoke Therapeutics' Board of Directors since September 2023. He currently serves as a senior advisor to Bain Capital Life Sciences, a position he has held since January 2021, and provides other advisory and consulting services to life science companies. He also sits on the Board of Directors for Rivus Pharmaceutical, Foghorn Therapeutics, Solid Biosciences, Alkeus Pharmaceuticals, iVexSol and Odyssey Therapeutics. He previously served as Executive Vice President and Chief Operating Officer, and Chief Financial Officer of Vertex Pharmaceuticals between 2001 and 2019. Prior to 2001, Mr. Smith was a partner in the Life Science and Technology Practice of the accounting firm Ernst & Young LLP.

Arthur Tzianabos, Ph.D. Biography

Dr. Arthur Tzianabos is CEO of Lifordi Immunotherapeutics and a venture partner at 5AM Ventures. He was previously CEO and later Chair of the Board of Directors at Homology Medicines, where he led the company from inception through a successful public offering. While at Homology, Dr. Tzianabos led efforts to develop genetic medicines by leveraging its in vivo gene therapy and nuclease-free gene editing platform for patients with rare genetic diseases. Dr. Tzianabos currently serves on the Board of Directors of Q32 Bio following its merger with Homology earlier this year. He was formerly Chair of the Board of Directors of Akouos, a publicly traded gene therapy company acquired by Lilly in 2022. Prior to this, he spent nine years at Shire, where he worked on the development and launches of multiple treatments for patients with rare genetic disorders and worked closely with the business development team to build Shire's product pipeline through investments and acquisitions.

Earlier in his career, Dr. Tzianabos was a principal investigator and faculty member at Harvard Medical School for 15 years, reaching the rank of associate professor of medicine and maintaining laboratories at the Channing Laboratory, Brigham and Women's Hospital and the Department of Microbiology and Molecular Genetics at Harvard Medical School. He has published more than 80 scientific papers, reviews, book chapters and patents. He holds a B.S. in biology from Boston College and a Ph.D. in microbiology from the University of New Hampshire.

Edward M. Kaye, M.D. Biography

Ed Kaye's decades-long career has always centered around helping children with severe diseases, resulting in seven approved medicines that have helped change the lives of tens of thousands of people. Trained in pediatrics, pediatric neurology and biochemical genetics with a B.S. in biology from Loyola University and an M.D. from the Loyola University Stritch School of Medicine, he was on the research staff at Massachusetts General Hospital and Tufts University Medical Center and was the chief of biochemical genetics at the Children's Hospital of Philadelphia. He was on the pediatric neurology staff at Boston Children's Hospital until 2021. In 2001, Dr. Kaye started the next phase of his career where he focused on translating promising science into new medicines for severe genetic diseases. He spent 10 years at Genzyme Corporation, most recently as group vice president of clinical development, where he supervised clinical research in programs focused on lysosomal storage disease and genetic neurological disorders. At Genzyme, Dr. Kaye also held various roles, including vice president of medical affairs for lysosomal storage diseases, vice president of clinical research and interim head of PGH global medical affairs. In 2011, he joined Sarepta Therapeutics as Chief Medical Officer leading the drive to develop Exondys 51 a pioneering drug for Duchenne muscular dystrophy. He went on to serve as CEO of Sarepta in 2015, where he led the successful push to win FDA approval of Exondys 51. He also served on Sarepta's Board of Directors. Dr. Kaye has served as Stoke's CEO and Director since 2017. He currently serves as a member of the Boards of Directors at Cytokinetics, Inc., Avidity Biosciences and the Massachusetts Biotechnology Council.

About Stoke Therapeutics

Stoke Therapeutics (Nasdaq: STOK), is a biotechnology company dedicated to restoring protein expression by harnessing the body's potential with RNA medicine. Using Stoke's proprietary TANGO (Targeted Augmentation of Nuclear Gene Output) approach, Stoke is developing antisense oligonucleotides (ASOs) to selectively restore naturally occurring protein levels. Stoke's first medicine in development, zorevunersen, has demonstrated the potential for disease modification in patients with Dravet syndrome and is expected to enter Phase 3 development in 2025. Stoke's initial focus are diseases of the central nervous system and the eye that are caused by a loss of ~50% of normal protein levels (haploinsufficiency). Proof of concept has been demonstrated in other organs, tissues, and systems, supporting broad potential for the Company's proprietary approach. Stoke is headquartered in Bedford, Massachusetts with offices in Cambridge, Massachusetts. For more information, visit https://www.stoketherapeutics.com/.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: the design, timing and results of the Phase 3 study; the timing and expected progress of regulatory filings and regulatory decisions; the ability of zorevunersen to treat the underlying causes of Dravet syndrome and reduce seizures or show improvements in behavior and cognition at the indicated dosing levels or at all; and the expectations regarding the collaborations. Statements including words such as "anticipate," "expect," "plan," "will," or "may" and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they prove incorrect or do not fully materialize, could cause the Company's results to differ materially from those expressed or implied by such forward-looking statements, including, but not limited to, risks and uncertainties related to: the Company's ability to advance, obtain regulatory approval and ultimately commercialize its product candidates; that if Biogen were to breach or terminate the collaboration, the Company would not obtain the anticipated financial or other benefits; the possibility that the Company and Biogen may not be successful in their development of zorevunersen and that, even if successful, they may be unable to successfully commercialize zorevunersen; positive results in a clinical trial may not be replicated in subsequent trials or successes in early stage clinical trials may not be predictive of results in later stage trials; the Company's ability to protect its intellectual property; the Company's ability to fund development activities and achieve development goals through mid-2028; and the other risks and uncertainties described under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2024, its quarterly reports on Form 10-Q, and the other documents it files with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

View source version on businesswire.com: https://www.businesswire.com/news/home/20250318206755/en/

Stoke Media & Investor Contacts:
Dawn Kalmar
Chief Communications Officer
dkalmar@stoketherapeutics.com
781-303-8302

Doug Snow
Director, Communications & Investor Relations
IR@stoketherapeutics.com
508-642-6485

Source: Stoke Therapeutics, Inc.