January 12, 2026

Achieve Life Sciences Confirms Promotion of Dr. Mark Rubinstein to Chief Medical Officer

Experienced medical executive advances to permanent role following successful leadership as Interim CMO

SEATTLE and VANCOUVER, British Columbia, Jan. 12, 2026 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a late-stage specialty pharmaceutical company focused on the global development and commercialization of cytisinicline for treatment of nicotine dependence for smoking cessation, today announced that it has confirmed the promotion of Mark Rubinstein, M.D., from Interim Chief Medical Officer to Chief Medical Officer (CMO).

Since Dr. Rubinstein began his tenure as Interim CMO in September 2025, the company has achieved significant clinical and regulatory milestones, and he co-authored the recent paper in *Thorax* of data demonstrating cytisinicline's potential efficacy and tolerability for smoking cessation in individuals with COPD.

"Dr. Rubinstein has been an excellent addition to our leadership team during this pivotal period," said Rick Stewart, President and Chief Executive Officer of Achieve Life Sciences. "His reputation and expertise in nicotine cessation strengthens our medical leadership as we advance toward regulatory review. We are pleased to confirm his appointment to the permanent CMO role, and we're confident the team will continue to drive our progress forward."

Dr. Rubinstein brings more than two decades of experience in clinical medicine, scientific research, and medical affairs leadership, with a strong focus on nicotine cessation and preventive medicine. Prior to joining Achieve as Head of Medical Affairs in October 2024, he served as Head of Medical Affairs at Blip, where he led medical strategy to support smoking and vaping cessation. Dr. Rubinstein is Professor Emeritus of Pediatrics at the University of California, San Francisco (UCSF), where he served on the faculty for nearly 20 years and conducted NIH-funded research advancing understanding of adolescent nicotine addiction and smoking cessation interventions. He earned his M.D. from Yale School of Medicine,

completed his Internal Medicine residency at Yale–New Haven Hospital, and is board-certified in Internal Medicine and Adolescent Medicine.

"I am honored to step into the permanent Chief Medical Officer role at this transformative time for Achieve and for patients struggling with nicotine dependence," said Dr. Mark Rubinstein, Chief Medical Officer of Achieve Life Sciences. "The robust safety profile demonstrated by our long-term trial data underscores the potential of cytisinicline to address an important unmet medical need, provide patients with new tools to successfully win their battle with addiction, and reduce the impact of comorbidities associated with nicotine dependence. I look forward to continuing to support our clinical and medical affairs teams as we move forward with the FDA review process."

About Achieve Life Sciences, Inc.
Achieve Life Sciences, Inc. is a late-stage specialty pharmaceutical company focused on the global development and commercialization of cytisinicline as a treatment of nicotine dependence. In September 2025, the company announced that its New Drug Application, submitted to the U.S. Food and Drug Administration (FDA) in June 2025, had been accepted for review. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) date of June 20, 2026. The NDA is for cytisinicline to be used as a treatment of nicotine dependence for smoking cessation in adults, based on two successfully completed Phase 3 studies and its open-label safety study. Additionally, the company has completed a Phase 2 study with cytisinicline in vaping cessation and conducted a successful end-of-Phase 2 meeting with the FDA for a future vaping indication.

About Cytisinicline
There are approximately 29 million adults in the United States who smoke combustible cigarettes.[1] Tobacco use is currently the leading cause of preventable death that is responsible for more than eight million deaths worldwide and nearly half a million deaths in the United States annually.[2,3] More than 87% of lung cancer deaths, 61% of all pulmonary disease deaths, and 32% of all deaths from coronary heart disease are attributable to smoking and exposure to secondhand smoke.[3]

In addition, there are approximately 17 million adults in the United States who use e-cigarettes, also known as vaping.[4] In 2024, approximately 1.6 million middle and high school students in the United States reported using e-cigarettes.[5] There are no FDA-approved treatments indicated specifically as an aid to nicotine e-cigarette cessation. FDA has awarded the Commissioner’s National Priority Voucher for e-cigarette or vaping cessation and granted Breakthrough Therapy designation to address this critical need.

Cytisinicline is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to aid in treating nicotine addiction for smoking and e-cigarette cessation by interacting with nicotine receptors in the brain, reducing the severity of nicotine craving symptoms, and reducing the reward and satisfaction associated with nicotine products. Cytisinicline is an investigational product candidate being developed as a treatment of nicotine dependence for smoking cessation and has not been approved by the FDA for any indication in the United States.

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, statements Achieve makes regarding the timing and nature of cytisinicline clinical

development and regulatory review and approval, data results and commercialization activities, the potential market size for cytisinicline, the potential benefits, efficacy, safety and tolerability of cytisinicline, the development and effectiveness of new treatments, and the successful commercialization of cytisinicline. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Achieve may not actually achieve its plans or product development goals in a timely manner, if at all, or otherwise carry out its intentions or meet its expectations or projections disclosed in these forward-looking statements. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including Achieve's Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q. Achieve undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof, other than as may be required by applicable law.

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Source: Achieve Life Sciences