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Achieve Life Sciences Names Dr. Mark Rubinstein Interim Chief Medical Officer

SEATTLE and VANCOUVER, British Columbia, Sept. 11, 2025 (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 Mark Rubinstein, M.D., will assume the role of Interim Chief Medical Officer (CMO). Dr. Rubinstein will succeed Cindy Jacobs, Ph.D., M.D., who we anticipate will provide advisory services to support the company's ongoing efforts to advance cytisinicline as a potential treatment option for nicotine dependence.

Dr. Rubinstein is a seasoned medical executive with deep experience in clinical development and medical affairs. Prior to joining Achieve Life Sciences as Head of Medical Affairs in October 2024, Dr. Rubinstein served as the Head of Medical Affairs at Blip, where he spearheaded the company's strategy to help smokers and vapers quit through FDA-approved medications and digital support tools. He was also Vice President of Global Scientific Affairs at Juul Labs, where he led efforts to prevent youth usage of nicotine products. 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. Dr. Rubinstein earned his M.D. from Yale University and completed his residency in Internal Medicine at Yale-New Haven Hospital.

"We thank Cindy for her many contributions to Achieve Life Sciences. We are pleased to appoint Mark to this critical role and know that his leadership will ensure long-term success as we work to solve the public health crisis of nicotine dependence," said Rick Stewart, CEO of Achieve Life Sciences. "We recently received FDA acceptance of our cytisinicline New Drug Application, and we are on track with our clinical, regulatory and commercialization objectives. We remain confident in the potential for cytisinicline as a smoking cessation treatment for the estimated 15 million American adults who attempt to quit each year."

About Achieve Life Sciences, Inc.

Achieve Life Sciences is a late-stage specialty pharmaceutical company committed to addressing the global smoking health and nicotine dependence epidemic through the development and commercialization of cytisinicline. In September 2025, the FDA accepted the cytisinicline New Drug Application (NDA) and defined a PDUFA completion date of June

20, 2026. 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. Cytisinicline has been granted Breakthrough Therapy designation by the FDA to address this critical unmet need.

Cytisinicline is a plant-derived alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to aid in treating nicotine dependence for smoking cessation 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 a new investigational product candidate being developed for the treatment of nicotine dependence for smoking cessation and has not been approved by the Food and Drug Administration 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 regarding anticipated changes to management, the timing and nature of cytisinicline clinical development and regulatory review and approval, the potential benefits, efficacy, safety and tolerability of cytisinicline, the ability to drive financial results and stockholder value, 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, among others, the risk that cytisinicline may not demonstrate the hypothesized or expected benefits; the risk that Achieve may not be able to obtain additional financing to fund the development and commercialization of cytisinicline; the risk that cytisinicline will not receive regulatory approval or be successfully commercialized; the risk that new developments in the smoking cessation landscape require changes in business strategy or clinical development plans; the risk that Achieve’s intellectual property may not be adequately protected; general business and economic conditions; risks related to the impact on our business of macroeconomic and geopolitical conditions, including inflation, volatile interest rates, volatility in the debt and equity markets, actual or perceived instability in the global banking system, global health

crises and pandemics and geopolitical conflict and the other factors described in the risk factors set forth in Achieve's filings with the Securities and Exchange Commission from time to time, 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.

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References

¹VanFrank B, Malarcher A, Cornelius ME, Schechter A, Jamal A, Tynan M. Adult Smoking Cessation — United States, 2022. MMWR Morb Mortal Wkly Rep 2024;73:633–641.

²World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017.

³U.S. Department of Health and Human Services. The Health Consequences of Smoking – 50 Years of Progress. A Report of the Surgeon General, 2014.

⁴Vahratian A, Briones EM, Jamal A, Marynak KL. Electronic cigarette use among adults in the United States, 2019–2023. NCHS Data Brief, no 524. Hyattsville, MD: National Center for Health Statistics. 2025. DOI: [https://dx.doi.org/ 10.15620/cdc/174583](https://dx.doi.org/10.15620/cdc/174583).

⁵Jamal A, Park-Lee E, Birdsey J, et al. Tobacco Product Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:917–924.



Source: Achieve Life Sciences