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Achieve Life Sciences Strengthens Leadership with Appointment of Dr. Mark Rubinstein, Nicotine Dependence Expert, as New Head of Medical Affairs

SEATTLE and VANCOUVER, British Columbia, Oct. 01, 2024 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a late-stage pharmaceutical company dedicated to the global development and commercialization of cytisinicline for smoking cessation and nicotine dependence, is pleased to announce the appointment of Dr. Mark L. Rubinstein as its new Head of Medical Affairs. Dr. Rubinstein brings more than two decades of experience in clinical medicine, scientific research, and medical affairs leadership, with a strong focus on preventative medicine and nicotine cessation.

As a seasoned medical executive and physician, Dr. Rubinstein's expertise aligns with Achieve Life Sciences' mission to provide innovative solutions for those struggling with nicotine dependence. His extensive career spans both academic and corporate settings, positioning him as a leading voice in nicotine addiction research and intervention.

"We are thrilled to welcome Mark to our team at this pivotal time," said Rick Stewart, CEO of Achieve Life Sciences. "His vast experience in smoking and vaping cessation, combined with his leadership in medical affairs, will play an instrumental role in shaping the future of our initiatives aimed at reducing nicotine dependence and improving public health outcomes."

Prior to joining Achieve, 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.

"I am honored to join Achieve at such an exciting time as we move closer to anticipated FDA approval and commercialization," said Dr. Rubinstein. "Cytisinicline has the potential to be the first new treatment for nicotine dependence in nearly 20 years, marking a major milestone in the field. I am eager to contribute to the development of this breakthrough

therapy, which could provide a crucial, long-awaited solution for those striving to quit nicotine and improve their health.”

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. His research, funded by the NIH and other prestigious organizations, focused on nicotine addiction in adolescents and smoking cessation interventions, resulting in numerous high-profile studies published in leading scientific journals.

Dr. Rubinstein is also a recognized thought leader and speaker, having been featured in major media outlets including ABC Nightly News, NPR, The New York Times, and The Wall Street Journal. His passion for leveraging digital media to drive health behavior change and improve healthcare outcomes aligns with Achieve Life Sciences’ innovative approach to combating nicotine addiction.

Dr. Rubinstein earned his M.D. from Yale University and completed his residency in Internal Medicine at Yale-New Haven Hospital. He is board-certified in both Internal Medicine and Adolescent Medicine.

About Achieve and Cytisinicline

Achieve’s focus is to address the global smoking health and nicotine addiction epidemic through the development and commercialization of cytisinicline. There are approximately 29 million adults in the United States alone 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 over 11 million adults in the United States who use e-cigarettes, also known as vaping.⁴ In 2023, approximately 2.1 million middle and high school students in the United States reported using e-cigarettes.⁵ Currently, there are no FDA-approved treatments indicated specifically as an aid to nicotine e-cigarette cessation.

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 withdrawal symptoms, and reducing the reward and satisfaction associated with nicotine products. Cytisinicline is an investigational product candidate being developed for the treatment of nicotine addiction and has not been approved by the Food and Drug Administration for any indication in the United States. For more information visit [the Achieve website](#).

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 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 ability to discover and develop new uses for cytisinicline, including but not limited to as an e-cigarette cessation product, and the development and effectiveness of

new treatments. 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 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

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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.

⁴Cornelius ME, Loretan CG, Jamal A, et al. Tobacco Product Use Among Adults – United States, 2021. MMWR Morb Mortal Wkly Rep 2023;72:475–483.

⁵Birdsey J, Cornelius M, Jamal A, et al. Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023. MMWR Morb Mortal Wkly Rep 2023;72:1173–1182.



Source: Achieve Life Sciences