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Achieve Life Sciences Announces Changes in Executive Leadership and Board of Directors

Richard Stewart reassumes role of Chief Executive Officer

Thomas King appointed Executive Chairman of the Board of Directors

SEATTLE and VANCOUVER, British Columbia, Aug. 26, 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, today announced that Mr. Richard (Rick) Stewart, Achieve's co-founder and current Executive Chairman, will reassume the role of Chief Executive Officer. John Bencich, who served as the Company's Chief Executive Officer for the past four years, will serve as an advisor during the transition. Additionally, the Company announced that Mr. Thomas (Tom) King, currently the lead independent director of the Board of Directors, will assume the role of Executive Chairman.

"The change in leadership is driven by the need to have a CEO with substantial M&A and commercial experience pushing the company forward to future critical milestones, whether that be a potential licensing transaction or strategic transaction for the commercialization of cytisinicline," commented Tom King, Executive Chairman of Achieve's Board of Directors. "On behalf of Achieve, we thank John for his tenure with the Company and appreciate his assistance during this transition."

"It's been an incredible journey helping Achieve grow over the past seven years and I wish the new leadership team continued success as they drive the cytisinicline program forward to patients," commented John Bencich. "I am thankful for the time I had at Achieve and all we accomplished, and am looking forward to pursuing my next opportunity."

Rick Stewart, Achieve Chief Executive Officer, added, "We remain on track to meet our objectives for this year, including the completion of enrollment of the ORCA-OL study, meeting with the FDA for our End-of-Phase 2 meeting for vaping cessation under Breakthrough Therapy designation, and furthering our progress on the NDA submission, that we expect to file in the first-half of 2025. I look forward to my new role and leading our

excellent team to bring forward a potentially life-changing treatment for millions of people who battle nicotine dependence, while at the same time aiming to optimize shareholder value.”

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 on cytisinicline and Achieve visit www.achievelifesciences.com.

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 entry into any licensing or other strategic transactions, 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, the development and effectiveness of new treatments, and the ability to drive shareholder value. 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, rising interest rates, increased 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, Schecter 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.

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