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Achieve Life Sciences Promotes Craig Donnelly to Chief Operations Officer

Donnelly brings more than 25 years of biopharmaceutical expertise in CMC and regulatory operations

SEATTLE and VANCOUVER, British Columbia, Sept. 18, 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 the promotion of Craig Donnelly to Chief Operations Officer.

Mr. Donnelly has been with Achieve since 2022, serving as Executive Vice President, Chemistry, Manufacturing, and Controls (CMC) and Regulatory CMC. In his expanded role as Chief Operations Officer, Mr. Donnelly will lead the integration of Achieve's supply chain and manufacturing activities with the commercial strategy in anticipation of a product launch in mid-late 2026. This responsibility involves optimizing operations efficiency in the company's manufacturing, supply chain, CMC operations and product life-cycle management, while ensuring the company maintains the highest standards of quality and regulatory compliance. His leadership will be essential in establishing the scalable commercial manufacturing processes and systems needed to support Achieve's transition from a late-stage development company to the anticipated commercial launch of cytisinicline.

"We are delighted to promote Craig to Chief Operations Officer," commented Rick Stewart, Chief Executive Officer of Achieve Life Sciences. "Craig's deep expertise and exceptional leadership have been instrumental in advancing our clinical and regulatory milestones. His ability to navigate the demands of bringing breakthrough therapeutics to market will be invaluable as we prepare for potential FDA approval of the first smoking cessation treatment in nearly two decades."

"I am honored to take on this expanded role as Chief Operations Officer during such an exciting period for Achieve Life Sciences," said Mr. Donnelly. "Cytisinicline represents a significant opportunity to address the unmet medical need in smoking cessation, and I look

forward to leveraging my experience to ensure we have the operations infrastructure and processes in place to deliver this important treatment to patients who need it most."

With more than 25 years of biopharmaceutical industry experience, Mr. Donnelly has expertise in both technical development and regulatory CMC at all stages of development. He previously held senior roles in CMC and regulatory functions at companies including NuCana, ICON (formerly Mapi), and F. Hoffman-La Roche. He began his career at Pfizer as an analytical chemist and advanced to a project leadership role. He also served as a Team Leader at Almac Sciences. He holds a Bachelor's with Honors in Chemical and Pharmaceutical Sciences from the University of Sunderland.

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 cessation 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 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, 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.

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>.

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