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Achieve Life Sciences Announces Operational Progress Including Completion of Technology Transfer to Adare Pharma Solutions

Adare Partnership Provides Supply Chain Redundancy and U.S.-based Manufacturing Capability

Company Reiterates Guidance - If Approved, Cytisinicline Commercial Launch Expected in First Half of 2027

SEATTLE and VANCOUVER, British Columbia, April 15, 2026 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Achieve or the Company) (Nasdaq: ACHV), a late-stage specialty pharmaceutical company focused on the global development and commercialization of cytisinicline as a treatment of nicotine dependence, today announced significant operational progress including the transfer of cytisinicline manufacturing to U.S.-based Adare Pharma Solutions (Adare). Achieve has now completed the analytical method transfer to Adare's manufacturing facility in Vandalia, Ohio. Completion of these activities ensures that all testing procedures are fully qualified at the site, maintaining the highest standards of quality control and regulatory compliance.

Achieve confirms that its first cytisinicline engineering batch has been manufactured at Adare. This initial manufacturing run is a vital precursor to registration and, ultimately, production at commercial scales and volumes.

"The completion of the analytical transfer and the first batch now in the manufacturing site firmly positions Achieve to meet the goal of manufacturing cytisinicline drug product in the U.S.," said Rick Stewart, Chief Executive Officer of Achieve Life Sciences. "This rapid progress reflects the sense of urgency for a strong domestic supply chain given the significant tariffs recently announced on imported pharmaceutical products and the growing imperative for supply chain resilience."

"We are excited to have partnered with Achieve, reflecting our shared commitment to advancing transformative therapies and delivering meaningful impact for patients in need,"

said Tom Sellig, Chief Executive Officer of Adare Pharma Solutions and member of the Achieve Board of Directors since 2023. “We are proud of what we have accomplished together thus far, and we remain deeply committed to supporting Achieve as their cytisinicline program progresses toward making a difference in patients’ lives.”

As previously disclosed, the U.S. Food and Drug Administration (FDA) identified observations during a current Good Manufacturing Practice (cGMP) inspection of the Company's third-party manufacturing facility. Achieve has recently been informed that the facility received an Official Action Indicated (OAI) classification from that inspection. The observations resulting in the OAI classification relate to general cGMP matters at the facility and are not specific to cytisinicline.

Achieve expects to receive a Complete Response Letter from the FDA on or before its June 20, 2026 Prescription Drug User Fee Act goal date. The Company intends to resubmit the New Drug Application naming Adare Pharma Solutions as its manufacturer for commercial supply in the fourth quarter of 2026. The Company reiterates its expectation of a cytisinicline launch in the first half of 2027.

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 Adare Pharma Solutions
Adare Pharma Solutions is a global technology-driven contract development and manufacturing organization (CDMO) providing end-to-end integrated services, from product development through commercial manufacturing and packaging, with small molecule expertise focusing on oral dosage forms for the pharmaceutical industry. Adare’s specialized technology platforms provide taste masking, customized release, multiparticulate systems, and patient-centric dosing solutions. With a proven history in drug delivery, Adare’s facilities in the US and Europe have developed and manufactured more than 65 products sold by customers worldwide.

About Cytisinicline
There are approximately 25 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]

In addition, there are nearly 18 million adults in the United States who use e-cigarettes, also known as vaping.[1] In 2024, approximately 1.6 million middle and high school students in the United States reported using e-cigarettes.[4] 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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[2]World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017.

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

[4]Jamal 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