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Achieve Life Sciences Announces Proposed Underwritten Public Offering

SEATTLE and VANCOUVER, British Columbia, June 26, 2025 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a late-stage specialty pharmaceutical company focused on the global development and commercialization of cytisinicline as a treatment of nicotine dependence for smoking cessation, today announced a proposed underwritten public offering in which it intends to offer and sell shares of its common stock (or pre-funded warrants to purchase common stock in lieu thereof) and accompanying common warrants to purchase common stock (or pre-funded warrants to purchase common stock in lieu thereof). In addition, Achieve intends to grant the underwriters a 30-day option to purchase up to an additional 15% of the shares of common stock and/or accompanying common warrants to purchase common stock (or pre-funded warrants to purchase common stock in lieu thereof) offered in the public offering. All of the securities are being offered by Achieve. The offering is subject to market and other conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

Citizens Capital Markets and Raymond James are acting as the joint book-running managers for the proposed offering. Lake Street Capital Markets, LLC is acting as financial advisor to Achieve in the proposed offering.

Achieve intends to use the proceeds from the offering to fund continued advancement of cytisinicline through potential U.S. Food and Drug Administration marketing approval of cytisinicline and for working capital and general corporate purposes.

The securities are being offered by Achieve pursuant to a registration statement on Form S-3 previously filed and declared effective by the Securities and Exchange Commission (SEC). A preliminary prospectus supplement and accompanying prospectus relating to this offering will be filed with the SEC. When available, copies of the preliminary prospectus supplement and the accompanying prospectus relating to this offering may be obtained from: Citizens Capital Markets, 450 Park Avenue, 5th Floor, New York, NY 10022, or by calling (415) 835-8985, or by email at syndicate@jmpsecurities.com and Raymond James at Equity Syndicate, 880 Carillon Parkway, St. Petersburg, Florida 33716, by telephone at (800) 248-8863, or by email at prospectus@raymondjames.com. Electronic copies of the preliminary prospectus supplement and accompanying prospectus will also be available on the website

of the SEC at <http://www.sec.gov>. The final terms of the offering will be disclosed in a final prospectus supplement to be filed with the SEC.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy any securities of Achieve, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

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 June 2025, the company submitted its New Drug Application to the FDA for cytisinicline as a treatment of nicotine dependence for smoking cessation in adults, based on two successfully completed Phase 3 studies and its fully enrolled 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 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 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 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 Achieve’s intention to conduct an offering and sale of securities, the grant of the option to purchase additional securities, the ability to complete the offering and expected use of proceeds, 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. There can be no assurance regarding the completion of this offering. 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 those risks described in the risk factors set forth in 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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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>.

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