

February 29, 2024



## **Achieve Life Sciences Announces Pricing of up to \$124.2 Million Registered Direct Offering and Concurrent Private Placement**

***\$60 million financing upfront with up to an additional \$64.2 million tied to exercise of milestone-driven warrants***

***Upfront net proceeds to provide funds to conduct clinical development of cytisinicline through New Drug Application submission expected in 1H 2025, including the ORCA-OL trial***

***Aggregate net proceeds (assuming exercise of all milestone-driven warrants) expected to be sufficient to fund cytisinicline development through potential FDA approval***

SEATTLE, Wash. and VANCOUVER, British Columbia, Feb. 29, 2024 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a late-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine dependence, today announced that it has entered into a securities purchase agreement with new and existing investors to raise up to approximately \$124.2 million in gross proceeds that includes initial upfront funding of \$60.0 million and up to an additional approximately \$64.2 million upon exercise of milestone-driven warrants.

The financing includes participation from healthcare-dedicated investors, including Propel Bio Partners LLC, Nantahala Capital, and a large, life sciences-dedicated investor. The financing also includes participation from strategic investor Sopharma and certain members of the company's management team and board of directors.

Lake Street Capital Markets, LLC and JonesTrading Institutional Services LLC are acting as joint placement agents for the registered direct offering and concurrent private placement.

The purchase and sale will be completed, in part, via a registered direct offering of 13,086,151 shares of common stock at a price of \$4.585 per share. In a concurrent private

placement, the company will issue unregistered warrants to purchase up to 13,086,151 shares of common stock at an exercise price of \$4.906 per share (provided, however, that the purchaser may elect to exercise the warrants for pre-funded warrants in lieu of shares of common stock at an exercise price of \$4.906, minus \$0.001, the exercise price of each pre-funded warrant). These warrants will be immediately exercisable for shares of common stock or pre-funded warrants in lieu thereof, and will expire on the earlier of (i) three and one-half years following the date of issuance and (ii) 30 days following Achieve's public disclosure of the acceptance of a New Drug Application (NDA) for cytisinicline by the U.S. Food and Drug Administration (FDA) in a Day 74 Letter or equivalent correspondence.

The registered direct offering and the concurrent private placement are each expected to close on or about March 4, 2024, subject to customary closing conditions. The aggregate gross proceeds from the issuance of common stock in the registered direct offering are expected to be approximately \$60.0 million, prior to deducting placement agent fees and estimated offering expenses. The company intends to use the proceeds from the offering to fund clinical development of cytisinicline through NDA submission, expected in 1H 2025, including the ORCA-OL clinical trial, to fund other cytisinicline related research and clinical development activities and for working capital and general corporate purposes. If the milestone-driven warrants issued in the private placement are exercised in full, the company would receive \$64.2 million in additional proceeds. The company expects that the net proceeds from the registered direct offering and concurrent private placement, assuming the exercise of all of the milestone-driven warrants, will be sufficient to fund its development of cytisinicline into 2026 and through potential FDA approval.

The shares of common stock are being offered pursuant to a shelf registration statement on Form S-3 (File No. 333-261811), which was declared effective by the United States Securities and Exchange Commission ("SEC") on January 5, 2022.

The milestone-driven warrants being issued in the private placement, along with the securities underlying such milestone-driven warrants, are being offered in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), and/or Regulation D promulgated thereunder and have not been registered under the Securities Act, or applicable state securities laws. Accordingly, the milestone-driven warrants and underlying securities may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Securities Act and such applicable state securities laws.

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 such state or jurisdiction. A prospectus supplement relating to the registered shares of common stock will be filed by the company with the SEC. When available, copies of the prospectus supplement, together with the accompanying prospectus, can be obtained at the SEC's website at [www.sec.gov](http://www.sec.gov) or from Lake Street Capital Markets, LLC, Prospectus Department, 920 Second Avenue South, Suite 700, Minneapolis, Minnesota 55402 or by email at [info@lakestreetcm.com](mailto:info@lakestreetcm.com) or JonesTrading Institutional Services LLC, Attention: Equity Capital Markets, 325 Hudson Street, 6th Floor New York, New York 10013; email: [ecm@jonestrading.com](mailto:ecm@jonestrading.com).

### **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 an estimated 28

million adults in the United States alone who smoke combustible cigarettes.<sup>1</sup> 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.<sup>2,3</sup> 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.<sup>3</sup>

In addition, there are over 11 million adults in the United States who use e-cigarettes, also known as vaping.<sup>3</sup> In 2023, approximately 2.1 million middle and high school students in the United States reported using e-cigarettes.<sup>4</sup> 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.

### **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 completion of the offering, the expected net proceeds of the offering, the expected net proceeds upon exercise of the warrants, the intended use of the proceeds of the offering and the expected sufficiency of such proceeds to fund the development of cytisinicline through potential FDA approval. 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, risks regarding Achieve’s ability to satisfy closing conditions related to the offering; risks related to market conditions; 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 Achieve’s business of macroeconomic conditions, including inflation, rising interest rates, instability in the global banking sector, and public health crises, such as the COVID-19 pandemic, 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 law.

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**References**

<sup>1</sup>Cornelius ME, Loretan CG, Jamal A, et al. Tobacco Product Use Among Adults – United States, 2021. MMWR Morb Mortal Wkly Rep 2023;72:475–483.

<sup>2</sup>World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization, 2017.

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

<sup>4</sup>Birdsey 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