May 13, 2025

Achieve Life Sciences Reports First Quarter 2025 Financial Results and Highlights Updates in Cytisinicline Program

Reiterates Planned Submission of an NDA for Cytisinicline to FDA in June 2025

Company to Host Conference Call at 8:30 AM EDT Today, Tuesday, May 13, 2025

SEATTLE and VANCOUVER, British Columbia, May 13, 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 its financial results for first quarter 2025 and confirmed that it plans to submit the upcoming New Drug Application (NDA) for cytisinicline to the U.S. Food and Drug Administration (FDA) in June 2025.

“The Achieve team is fully committed to finalizing the NDA for submission to the FDA next month. This pivotal milestone is the culmination of our team’s tireless efforts. It marks a critical inflection point as we move towards delivering the first new FDA-approved treatment for smoking cessation in nearly 20 years,” said Rick Stewart, Chief Executive Officer of Achieve. “Cytisinicline has the potential to have a significant benefit on U.S. public health with patients and their healthcare providers needing new options to improve cessation outcomes.”

Recent Highlights

- Announced publication of the second Phase 3 ORCA-3 trial results in the *Journal of American Medical Association (JAMA) Internal Medicine* that evaluated cytisinicline for smoking cessation in 792 U.S. adults
- Reached key requirements in the ORCA-OL long-term exposure trial including safety exposure data for ≥300 participants receiving six months and at least 100 participants receiving one year of cumulative cytisinicline treatment
- Completed third safety review of the ORCA-OL clinical trial with the Data Safety Monitoring Committee (DSMC), which did not identify any safety concerns with longer-

term cytisinicline exposure
- Conducted a Science Advisory Board (SAB) meeting with leading experts in nicotine and tobacco cessation research

“Reaching 100 patients with one year of cumulative treatment in the ORCA-OL long-term exposure trial without safety issues further reinforces cytisinicline’s tolerability and differentiates it from currently available treatments,” commented Dr. Cindy Jacobs, President and Chief Medical Officer of Achieve. “Currently, approximately 75% of the 479 enrolled participants remain on treatment, speaking to cytisinicline’s overall benefit and the potential to shift the treatment paradigm for smoking cessation.”

Published Phase 3 ORCA-3 Trial Results in *JAMA Internal Medicine*
Complete results from the Phase 3 ORCA-3 clinical trial have been published in *JAMA Internal Medicine*, further validating cytisinicline as a potential treatment for smoking cessation. The randomized, placebo-controlled trial enrolled 792 U.S. adult smokers, and reaffirmed cytisinicline’s efficacy and tolerability at both 6- and 12-week treatment durations, including reduction in nicotine cravings and extended quit rates through 24 weeks. These findings, consistent with results from the ORCA-2 trial, further support cytisinicline’s targeted effect on treating nicotine dependence by selectively binding to nicotine receptors.

Reached FDA’s Long-term Exposure Requirements in the ORCA-OL Clinical Trial
Achieve has successfully completed the FDA requirements of having safety data on more than 300 participants completing six months of cumulative cytisinicline treatment and on 100 participants completing one year of cumulative cytisinicline treatment. The ORCA-OL clinical study enrolled 479 participants across 29 U.S. sites. This study is evaluating the long-term safety of the 3 mg cytisinicline regimen for smoking and vaping cessation, a key requirement for Achieve’s NDA submission planned in June 2025.

Announced Completion of Third DSMC Review on Safety Data for ORCA-OL Clinical Trial
Following its third comprehensive review of safety data from the ongoing ORCA-OL long-term exposure clinical trial, the DSMC reported no unexpected treatment-related adverse events and continued to note excellent participant adherence to cytisinicline. The overall safety data remain consistent with previous findings, and the DSMC recommended that the study continue as planned with no changes.

Conducted SAB Meeting
In May, Achieve convened an SAB meeting, including ten leading experts in nicotine and tobacco cessation research. This meeting provided an opportunity to share updates on clinical progress and NDA preparations for cytisinicline, while also benefiting from the insights of some of the foremost researchers in the field.

Financial Results
As of March 31, 2025, the company’s cash, cash equivalents, and marketable securities were $23.2 million. Total operating expenses for the quarter ended March 31, 2025 were $12.9 million. Total net loss for the quarter ended March 31, 2025 was $12.8 million.

Conference Call Details
Achieve will host a conference call at 8:30 am EDT today, Tuesday, May 13, 2025. To access the webcast, please use the following link: 1Q25 Earnings Webcast. Alternatively, you may access the live conference call by dialing 877-269-7756 (U.S. & Canada) or 201-

689-7817 (International), referencing conference ID 13752599. A webcast replay will be available approximately three hours after the call and archived on the website for 90 days.

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. The company has successfully completed two Phase 3 studies with cytisinicline for smoking cessation and one Phase 2 study with cytisinicline in vaping cessation. The company has fully enrolled its ongoing open-label safety study with cytisinicline and plans to submit its new drug application for smoking cessation in June 2025. Achieve has also 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 over 11 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 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 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, 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 in a timely manner or at all, or be successfully commercialized; the risk that new developments in the smoking and vaping cessation landscapes 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 fluctuating inflation, interest and tariff 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

[1]VanFrank 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.

[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]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.

[5]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

Consolidated Statements of Loss
(In thousands, except per share and share data)

	Three months ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	7,097	2,799
General and administrative	5,797	3,183
Total operating expenses	12,894	5,982
Loss from operations	(12,894)	(5,982)
Other income (expense)	67	(512)
Net loss	$ (12,827)	$ (6,494)

Basic and diluted net loss per share	$ (0.37)	$ (0.26)
Weighted average number of basic and diluted common shares	34,685,072	25,048,134

Consolidated Balance Sheets
(In thousands)

	March 31, 2025	December 31, 2024
Assets:		
Cash, cash equivalents and short-term investments	$ 23,245	$ 34,360
Prepaid expenses and other current assets	1,755	2,107
Other assets and restricted cash	300	39
Right-of-use assets	106	119
License agreement	918	974
Goodwill	1,034	1,034
Total assets	$ 27,358	$ 38,633
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 5,879	$ 6,627
Current portion of long-term obligations	57	55
Current portion of convertible debt	1,194	—
Non-current portion of convertible debt	8,657	9,837
Contingent consideration	1,240	1,149
Other long-term obligations	52	66
Stockholders' equity	10,279	20,899
Total liabilities and stockholders' equity	$ 27,358	$ 38,633

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Source: Achieve Life Sciences