May 9, 2023

Achieve Life Sciences Reports Financial Results for First Quarter 2023 and Provides Corporate Update

Company to host conference call at 4:30 PM EDT today, May 9, 2023

SEATTLE and VANCOUVER, British Columbia, May 09, 2023 (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 first quarter 2023 financial results and provided an update on the cytisinicline development program.

Recent Business Highlights

- Released positive Phase 2 ORCA-V1 clinical trial results showing statistically significant vaping cessation benefit for cytisinicline
- Announced accomplishment of key milestones, including last subject dosing and last subject visit, in the Phase 3 ORCA-3 trial evaluating cytisinicline for smoking cessation
- Presented additional analyses from the Phase 3 ORCA-2 trial at the Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting
- Appointed three new members to Achieve's Board of Directors

"We are excited about our start to 2023, announcing statistically significant trial results from ORCA-V1 in April, and on-track to report topline results from the Phase 3 ORCA-3 trial in the second quarter," stated John Bencich, Chief Executive Officer of Achieve. "We continue to believe in the tremendous potential of cytisinicline to become the first new FDA-approved treatment for smoking cessation in nearly twenty years, and now with the results of ORCA-V1, the possibility of becoming the first treatment specifically indicated for e-cigarette cessation."

ORCA-V1 E-Cigarette Cessation Benefit for Cytisinicline

Achieve announced successful results from the Phase 2 ORCA-V1 trial in April 2023. Trial participants who received 12 weeks of cytisinicline treatment had 2.6 times higher odds, or likelihood, to have quit vaping during the last 4 weeks of treatment compared to subjects who received placebo (p=0.035). The vaping cessation rate during weeks 9 through 12 was 31.8% for those who received cytisinicline treatment compared to 15.1% for those who received placebo. A benefit in favor of cytisinicline was consistently observed across the secondary endpoints and was observed across clinical trial sites and demographics such as age, gender, race, or whether they had smoked cigarettes in the past. Cytisinicline was well tolerated and no serious adverse events were reported.

Phase 3 ORCA-3 Last Subject Dosed/Last Subject Visit Completed
In January 2023 and March 2023, the final subject was dosed, and the last subject last visit was completed, respectively, in the ongoing Phase 3 ORCA-3 trial. ORCA-3 enrolled 792 adults who smoke cigarettes across 20 clinical trial locations in the United States. Study participants were randomized to receive either 6 or 12 weeks of cytisinicline treatment or placebo, and all participants received standard behavioral support for the duration of the study. The primary endpoint is biochemically verified continuous abstinence during the last four weeks of treatment and the trial will be determined successful if either cytisinicline treatment arm shows a statistical benefit compared to placebo. Topline results are on track to be reported in the second quarter of 2023.

Cytisinicline Data Presentation at SRNT Annual Meeting
In April 2023, additional analyses from the Phase-3 ORCA-2 trial were reported at the SRNT Annual Meeting confirming that successful smoking cessation was observed in subgroups of people who smoke that received cytisinicline, regardless of age, gender, smoking history, or previous quit attempts. Subjects who received either 6 or 12 weeks of cytisinicline treatment experienced consistently higher rates of smoking cessation. The improvement was observed by the second week of treatment and maintained weekly throughout study treatment and during the 24-week follow-up period; such improvement was not observed in those who received placebo. Study compliance was high with 82% of subjects completing the 12 weeks of treatment. No treatment-related serious adverse events were reported and the majority of adverse events were mild in all subjects.

Three New Members Appointed to Board of Directors
In March 2023, the Company announced a refresh to the Board of Directors with the appointment of three new directors, Mr. Stuart Duty, Mr. Thomas King, and Mr. Tom Sellig. The new directors bring extensive capital markets, strategic transaction, sales, marketing, and manufacturing expertise in the pharmaceutical and life sciences industries.

Financial Results
As of March 31, 2023, the Company's cash, cash equivalents, and restricted cash was $16.6 million. Total operating expenses for the first quarter ended March 31, 2023 were $8.6 million. Total net loss for the first quarter ended March 31, 2023 was $9.0 million. As of May 9, 2023, Achieve had 18,040,760 shares outstanding.

Conference Call Details
Achieve will host a conference call at 4:30 PM EDT today, Tuesday, May 9, 2023. To access the webcast, log on to the investor relations page of the Achieve website at http://ir.achievelifesciences.com/events-and-webcasts. Alternatively, access to the live conference call is available by dialing (866) 682-6100 (U.S. & Canada) or (862) 298-0702 (International) and referencing conference ID 13738142. A webcast replay will be available approximately two hours after the call and will be archived on the website for 90 days.

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. 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.[1,2] 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.[2]

In addition, there are over 11 million adults in the United States who use e-cigarettes, also known as vaping.[3] In 2022, approximately 2.5 million middle and high school students in the United States reported using e-cigarettes.[4] 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 timing and nature of cytisinicline clinical development, data results and commercialization activities, the potential market size for cytisinicline, the potential benefits, safety and tolerability of cytisinicline, the ability to discover and develop new uses for cytisinicline, including but not limited to as an e-cigarette cessation product, and the development and effectiveness of new treatments. 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 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 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.

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References

[1] World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019.*Geneva*: World Health Organization, 2017.

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

[3] 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.

[4] Park Lee E, Ren C, Cooper M, Cornelius M, Jamal A, Cullen KA. Tobacco Product Use Among Middle and High School Students – United States, 2022. Morbidity and Mortality Weekly Report, 2022; 71:45.

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

	Three months ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	5,534	4,388
General and administrative	3,044	2,838
Total operating expenses	8,578	7,226
Loss from operations	(8,578)	(7,226)
Other income (expense)	(414)	(347)
Net loss	$ (8,992)	$ (7,573)
Basic and diluted net loss per share	$ (0.50)	$ (0.80)
Weighted average number of basic and diluted common shares	17,917,769	9,458,745

Consolidated Balance Sheets
(In thousands)

	March 31, 2023	December 31, 2022
Assets:		
Cash and cash equivalents	$ 16,514	$ 24,771
Prepaid expenses and other current assets	1,710	2,559
Other assets and restricted cash	68	123
Right-of-use assets	109	66
License agreement	1,363	1,418
Goodwill	1,034	1,034
Total assets	$ 20,798	$ 29,971
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 3,872	$ 5,470
Current portion of long-term obligations	58	58
Convertible debt	16,371	16,071
Long-term obligations	54	69
Stockholders' equity	443	8,303
Total liabilities and stockholders' equity	$ 20,798	$ 29,971

Source: Achieve Life Sciences