March 16, 2023

Achieve Life Sciences Reports Financial Results for Fourth Quarter and Year-End 2022 and Provides Corporate Update

Company to host conference call March 16, 2023, at 4:30 PM EDT

SEATTLE, Wash. and VANCOUVER, British Columbia, March 16, 2023 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (NASDAQ: ACHV), a late-stage clinical pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine dependence, today announced fourth quarter and year-end 2022 financial results and provided an update on the cytisinicline development program.

Recent Highlights

- Presented additional analyses from the Phase 3 ORCA-2 trial at the Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting
- Announced accomplishment of key milestones, including last subject dosing and last subject visit, in the Phase 2 ORCA-V1 trial evaluating cytisinicline for e-cigarette cessation
- Completed dosing of final subject in the Phase 3 ORCA-3 trial of cytisinicline for smoking cessation
- Granted patent by United States Patent and Trademark Office (USPTO) for new cytisinicline formulation
- Closed financing of $18.9 million, prior to deducting placement agent commissions and estimated offering expenses

John Bencich, Chief Executive Officer of Achieve, commented, “We believe that cytisinicline has the potential to help millions of people overcome their dependence to nicotine, and ultimately, live better and healthier lives. We will continue to honor our commitment to the patients we serve, and the numerous stakeholders who share our confidence in cytisinicline, by delivering on our key milestones in the year ahead. We look forward to 2023 being the most pivotal and exciting year yet for Achieve.”

Phase 3 ORCA-2 Trial of Cytisinicline Presented at SRNT
New analyses from the ORCA-2 trial were presented as part of the "Novel Treatments for Smoking Cessation" session held March 3, 2023, at the Annual SRNT Meeting. The presentation, given by ORCA-2 Principal Investigator, Dr. Nancy Rigotti, highlighted successful abstinence rates observed in subgroups of smokers who received cytisinicline, regardless of age, gender, smoking history, or previous quit attempts. Additional findings also demonstrated consistently higher rates of abstinence in subjects who received either 6 or 12-weeks of cytisinicline, compared to placebo. The higher rates of abstinence were maintained throughout study treatment and during the 24-week follow-up period.

Phase 2 ORCA-V1 Last Subject Dosed/Last Subject Visit Completed
In January 2023 and February 2023, the final subject was dosed, and the last subject last visit was completed, respectively, in the ongoing Phase 2 ORCA-V1 trial. The ORCA-V1 trial, which is partially funded by the National Institute of Health (NIH), enrolled 160 adult users of nicotine e-cigarettes, or vapes, across five clinical trial locations in the United States. Participants were randomized in this two-arm trial to either receive 3 mg of cytisinicline three-times daily, or placebo for a period of 12 weeks. The primary outcome assessment is continuous vaping abstinence during the final four weeks of treatment. It was announced in early November 2022 that target enrollment in the trial was achieved ahead of schedule. Topline results are expected in the second quarter of 2023.

Phase 3 ORCA-3 Last Subject Dosed
The last subject was dosed in the second Phase 3 ORCA-3 trial in January 2023. The two-arm trial randomized 792 subjects across 20 clinical trial locations in the United States. Subjects are monitored through 24 weeks post randomization and receive standard behavioral support for the duration of treatment. Similar to the previously reported ORCA-2 trial, ORCA-3 is evaluating the smoking cessation efficacy, safety, and tolerability of 3 mg cytisinicline dosed three times daily for either 6 or 12 weeks compared with placebo. Topline results are expected in the second quarter of 2023.

Patent Granted by USPTO for New Cytisinicline Formulation
In December 2022, the USPTO issued U.S. Patent No. 11,459,328, which covers the mesylate salt formulation of cytisinicline and the process for its development. Achieve now has 15 patents and 46 pending patenting, including expirations extending out until 2042.

Private Placement of $18.9 Million
In November 2022, Achieve entered into a definitive agreement for a private placement of its securities for gross proceeds of approximately $18.9 million, prior to deducting placement agent commissions and estimated offering expenses. Participating in the private placement was a new life science focused investment fund, Achieve's management, and existing investors. The proceeds of the placement are being used to fund the ongoing trials, research and development, and for general working capital.

Financial Results
As of December 31, 2022, the company's cash, cash equivalents, and restricted cash was $24.8 million. Total operating expenses for the fourth quarter and year ended December 31, 2022 were $10.9 million and $40.8 million, respectively. Total net loss for the fourth quarter and year ended December 31, 2022 was $11.2 million and $42.4 million, respectively. As of March 16, 2023 Achieve had 17,930,362 shares outstanding.

Conference Call Details
Achieve will host a conference call at 4:30 PM EDT today, Thursday, March 16, 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 (877) 269-7756 (U.S. & Canada) or (201) 689-7817 (International) and referencing conference ID 13736451. 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 nearly 9 million adults in the United States who use e-cigarettes, also known as vaping.[3] While nicotine e-cigarettes are thought to be less harmful than combustible cigarettes, they remain addictive and can deliver harmful chemicals which can cause lung injury or cardiovascular disease.[4] In 2021, e-cigarettes were the most commonly used tobacco product reported by 1.72 million high school students.[5] Research shows adolescents who have used e-cigarettes are seven times more likely to become smokers one year later compared to those who have never vaped.[6] 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 treatment of nicotine addiction and has not been approved by the Food and Drug Administration for any indication in the United States. For more information on cytisinicline and Achieve visit www.achievelifesciences.com.

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 the COVID-19 pandemic or similar public health crises 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, Wang TW, Jamal A, Homa DM. Tobacco Product Use Among Adults — United States, 2020. MMWR Morb Mortal Wkly Rep 2022;71:397–405.

[4]Ogunwale, Mumiye A et al. (2017) Aldehyde Detection in Electronic Cigarette Aerosols. ACS omega 2(3): 1207-1214. DOI: 10.1021/acsomega.6b00489].

[5]Gentzke AS, Wang TW, Cornelius M, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021. MMWR Surveill Summ 2022;71(no. SS-5):1-29. DOI: 10.15585/mmwr.ss7105a1.

[6]Elizabeth C. Hair, Alexis A. Barton, Siobhan N. Perks, Jennifer Kreslake, Haijun Xiao, Lindsay Pitzer, Adam M. Leventhal, Donna M. Vallone, Association between e-cigarette use and future combustible cigarette use: Evidence from a prospective cohort of youth and young adults, 2017–2019, Addictive Behaviors, Volume 112, 2021, 106593, ISSN 0306-4603. DOI: 10.1016/j.addbeh.2020.106593.

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

	Three months ended December 31,		Twelve months ended December 31,	
	2022	**2021**	**2022**	**2021**

Operating expenses:				
Research and development	8,614	4,506	30,078	23,966
General and administrative	2,248	2,609	10,722	9,128
Total operating expenses	10,862	7,115	40,800	33,094
Loss from operations	(10,862)	(7,115)	(40,800)	(33,094)
Other income (expense)	(370)	(36)	(1,550)	(58)
Net loss	$ (11,232)	$ (7,151)	$ (42,350)	$ (33,152)
Basic and diluted net loss per share	$ (0.83)	$ (0.76)	$ (4.00)	$ (4.08)
Weighted average number of basic and diluted common shares	13,536,944	9,453,542	10,593,034	8,119,836

Consolidated Balance Sheets
(In thousands)

	December 31, 2022	December 31, 2021
Assets:		
Cash and cash equivalents	$ 24,771	$ 43,022
Prepaid expenses and other current assets	2,559	1,572
Other assets and restricted cash	66	183
Right-of-use assets	123	64
License agreement	1,418	1,641
Goodwill	1,034	1,034
Total assets	$ 29,971	$ 47,516
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 5,470	$ 4,481
Current portion of long-term obligations	58	69
Convertible debt	16,071	14,920
Long-term obligations	69	4
Stockholders' equity	8,303	28,042
Total liabilities and stockholders' equity	$ 29,971	$ 47,516

Source: Achieve Life Sciences