March 10, 2022

Achieve Life Sciences Reports Financial Results for Fourth Quarter and Year-End 2021 and Provides Corporate Update

Company to host conference call at 4:30 PM EST today, March 10, 2022

SEATTLE and VANCOUVER, British Columbia, March 10, 2022 (GLOBE NEWSWIRE) -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation and nicotine addiction, today announced fourth quarter and year-end 2021 financial results and provided an update on the cytisinicline clinical development program.

Recent Business Highlights

- Initiated ORCA-3, the second Phase 3 trial, in 750 adult smokers at 15 clinical sites in the United States
- Announced last subject and last follow-up visit in the Phase 3 ORCA-2 trial of cytisinicline for smoking cessation
- Entered into a $25 million loan facility with Silicon Valley Bank
- Facilitated Key Opinion Leader virtual roundtable on smoking and e-cigarette cessation
- Received U.S. Food and Drug Administration (FDA) acceptance of Investigational New Drug (IND) application for investigation of cytisinicline as a treatment for nicotine e-cigarette/vaping cessation

“We finished 2021 strong achieving multiple milestones and are starting the new year off with continued momentum in the cytisinicline development program,” commented John Bencich, Chief Executive Officer of Achieve. “We are eagerly anticipating topline results from the Phase 3 ORCA-2 trial in the coming months, as we enroll smokers in the recently initiated Phase 3 ORCA-3 trial at 15 clinical sites in the United States. Additionally, our cash position remains strong with funding into 2023, allowing us to execute on the final stages of clinical development needed to support an NDA for smoking cessation.”

Phase 3 ORCA-3 Trial Initiated
Achieve announced it has initiated enrollment for the Phase 3 ORCA-3 trial at 15 clinical

sites in the United States in January 2022. Similar to the ORCA-2 trial, ORCA-3 will evaluate the efficacy and safety of 3 mg cytisinicline dosed three times daily compared to placebo. Approximately 750 smokers will be randomized to one-of-three treatment arms to evaluate cytisinicline administered for either 6 or 12 weeks.

Phase 3 ORCA-2 Trial Completed Last Subject and Last Follow-up Visit
Achieve completed the last study follow-up visit for the last subject enrolled in the Phase 3 ORCA-2 trial in late December 2021. The ORCA-2 trial is the first Phase 3 trial in Achieve's ORCA (**O**ngoing **R**esearch of **C**ytisinicline for **A**ddiction) Program, designed to evaluate the smoking cessation effectiveness, safety, and tolerability of 3 mg cytisinicline taken three times daily for either 6 or 12 weeks, compared with placebo. ORCA-2 randomized 810 subjects across 17 clinical trial sites in the United States. Topline data regarding the primary results are expected in the second quarter of 2022.

$25 Million Loan Facility with Silicon Valley Bank
In December 2021, Achieve announced a $25 million debt agreement with Silicon Valley Bank and SVB Innovation Credit Fund VIII, L.P. (SVB). The proceeds and funds available under the debt agreement are expected to fund the completion of the cytisinicline smoking cessation clinical development program. SVB funded $15 million in the form of contingent convertible indebtedness and Achieve may borrow additional non-convertible term loans in an aggregate original principal amount of up to $10 million.

Virtual Smoking Cessation KOL Roundtable
Achieve hosted a Key Opinion Leader virtual roundtable on smoking and e-cigarette cessation in December 2021. Two esteemed smoking cessation experts discussed the current market for smoking and e-cigarette cessation, challenges with available treatments, and the potential of cytisinicline to be the first new FDA approved smoking cessation therapy in nearly two decades. Click here to view the event.

FDA Acceptance of IND for Cytisinicline in e-Cigarette and Vape Cessation
The FDA completed its review and accepted an IND application to investigate cytisinicline as a cessation treatment for nicotine e-cigarette users in November 2021. The Phase 2 ORCA-V1 study will enroll approximately 150 adult nicotine e-cigarette users in the United States and is expected to initiate in the second quarter of 2022. Grant funding to support the trial has been awarded in two phases from the National Institute on Drug Abuse of the National Institutes of Health. Completion of required milestones for the first phase of grant funding included the submission of the IND and clearance to proceed with the clinical trial by FDA. Achieve has submitted for completion of the first phase milestones and awaits clearance under the grant to proceed with ORCA-V1 study.

Financial Results
As of December 31, 2021, the company's cash, cash equivalents, and restricted cash was $43.1 million. Total operating expenses for the fourth quarter and year ended December 31, 2021 were $7.1 million and $33.1 million, respectively. Total net loss for the fourth quarter and year ended December 31, 2021 was $7.2 million and $33.2 million, respectively. As of March 10, 2022, Achieve had 9,460,835 shares outstanding.

Conference Call Details
Achieve will host a conference call at 4:30 PM EST today, Thursday, March 10, 2022. 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) 472-9809 (U.S. & Canada) or (629) 228-0791

(International) and referencing conference ID 8066623. 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

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] Achieve's focus is to address the global smoking health and nicotine addiction epidemic through the development and commercialization of cytisinicline. Cytisinicline is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to aid in smoking cessation by interacting with nicotine receptors in the brain by reducing the severity of nicotine withdrawal symptoms and by reducing the reward and satisfaction associated with smoking.

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 Russian military action in Ukraine; 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.

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

	Three months ended December 31,		Twelve months ended December 31,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	4,506	2,347	23,966	6,882
General and administrative	2,609	2,374	9,128	7,868
Total operating expenses	7,115	4,721	33,094	14,750
Loss from operations	(7,115)	(4,721)	(33,094)	(14,750)
Other income (expense)	(36)	(3)	(58)	20
Net loss	$ (7,151)	$ (4,724)	$ (33,152)	$ (14,730)
Basic and diluted net loss per share	$ (0.76)	$ (1.11)	$ (4.08)	$ (5.42)
Weighted average number of basic and diluted common shares	9,453,542	4,266,432	8,119,836	2,718,909

Consolidated Balance Sheets
(In thousands)

	December 31,	December 31,

	2021	2020
Assets:		
Cash and cash equivalents	$ 43,022	$ 35,853
Prepaid expenses and other current assets	1,572	1,122
Property, equipment, other assets and restricted cash	183	279
Right-of-use assets	64	146
License agreement	1,641	1,864
Goodwill	1,034	1,034
Total assets	$ 47,516	$ 40,298
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 4,481	$ 2,843
Current portion of long-term obligations	69	92
Convertible debt	14,920	—
Long-term obligations	4	77
Stockholders' equity	28,042	37,286
Total liabilities and stockholders' equity	$ 47,516	$ 40,298

Source: Achieve Life Sciences