May 13, 2021

Achieve Reports Financial Results for First Quarter 2021 and Provides Corporate Update

SEATTLE, WA and VANCOUVER, BC / ACCESSWIRE / May 13, 2021 /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 first quarter 2021 financial results and provided an update on the cytisinicline clinical development program.

Recent Events & Highlights

- Provided update on the Phase 3 ORCA-2 clinical trial evaluating the efficacy and safety of 3.0 mg cytisinicline dosed 3 times daily compared to placebo in 750 adult smokers at 17 clinical sites in the United States
- Published Phase 2b ORCA-1 safety, efficacy, and compliance results in *Nicotine and Tobacco Research*
- Announced the appointment of Dr. Bridget Martell and Dr. Cindy Jacobs to Achieve's Board of Directors
- Published RAUORA Head-to-Head Non-Inferiority Clinical Trial Comparing Cytisinicline and Chantix® (varenicline) in *Addiction*

"In the first quarter, we've seen great interest and increased momentum in the ORCA-2 trial and look forward to completing enrollment by the middle of the year," commented John Bencich, Chief Executive Officer of Achieve. "We will continue to focus our efforts on execution of the Phase 3, ensuring all required NDA-enabling activities remain on track, and furthering our discussions with potential strategic partners to prepare for cytisinicline commercialization."

Phase 3 ORCA-2 Trial

The Phase 3 ORCA-2 trial continues to enroll at 17 clinical sites in the United States. Approximately 750 adult smokers will be randomized to one of three study arms to determine the efficacy and safety of cytisinicline administered for either six or twelve weeks, compared to placebo. The primary endpoint is biochemically verified continuous abstinence during the last four weeks of treatment in the six and twelve-week cytisinicline treatment arms compared to placebo. Each treatment arm will be compared independently to the placebo arm and the trial will be determined to be successful if either or both of the cytisinicline treatment arms show a statistical benefit compared to placebo. The trial is expected to complete enrollment by the middle of 2021.

ORCA-1 Results Published in *Nicotine and Tobacco Research*

Results from the Phase 2b ORCA-1 trial were published in the scientific journal *Nicotine and Tobacco Research.* ORCA-1 evaluated the efficacy and safety of cytisinicline across various

dosing and administration schedules in 254 smokers in the United States. The publication reported that subjects treated with cytisinicline, regardless of dose or schedule, had statistically significantly higher ($p<0.001$) end of treatment abstinence rates compared to those treated with placebo. Participants in the 3.0 mg cytisinicline 3 times daily (TID) arm, were five times more likely to quit smoking than those in the placebo arm (OR of 5.04, 95% CI: 1.42, 22.32, $p<0.001$). Cytisinicline was well-tolerated with no serious or severe adverse events (AEs) reported.

Appointment of Drs. Martell and Jacobs to Board of Directors

Achieve announced the appointment of two new members to Achieve's Board of Directors, Dr. Bridget Martell and Dr. Cindy Jacobs. Dr. Martell is board certified in both Internal and Addiction Medicine and is an experienced executive leader in the pharmaceutical industry. Dr. Jacobs serves as Achieve's President and Chief Medical Officer, and in addition to her Board of Directors duties, will continue in her current role leading Achieve's regulatory and clinical development efforts for cytisinicline.

RAUORA Trial Results Published in *Addiction*

Results from the Phase 3 RAUORA trial were published in the scientific journal *Addiction*. RAUORA evaluated the effectiveness and safety of cytisinicline compared to Chantix® (varenicline) as a smoking cessation aid in 679 indigenous New Zealanders (Māori). The published results indicate that cytisinicline met the pre-specified non-inferiority endpoint, and was trending towards superiority with an Absolute Risk Difference of +4.29 in favor of cytisinicline (95% CI -0.22 to 8.79), and a 55% improvement in quit rates at six months in favor of cytisinicline when compared to Chantix. A Bayesian analysis of the primary efficacy outcome is ongoing. Additionally, statistically significant fewer overall AEs were reported in cytisinicline-treated subjects (Relative Risk 0.56, 95% CI 0.49 to 0.65, $p<0.001$) including a significantly lower rate of nausea when compared to subjects on Chantix.

Financial Results

As of March 31, 2021, the company's cash, cash equivalents, and restricted cash was $29.7 million. Total operating expenses for the three months ended March 31, 2021 was $8.0 million. Total net loss for the three months ended March 31, 2021 was $8.0 million.

As of May 13, 2021, Achieve had 6,164,360 shares outstanding.

Conference Call Details

Achieve will host a conference call at 4:30 pm Eastern time today, Thursday, May 13, 2021. 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 6096445. A webcast replay will be available approximately two hours after the call and will be archived on the website for 90 days.

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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.

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 commercialization activities, the potential market size for cytisinicline, the potential benefits 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.

Chantix® is a registered trademark of Pfizer, Inc.

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

	Three months ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	5,642	1,541
General and administrative	2,342	1,816
Total operating expenses	7,984	3,357
Loss from operations	(7,984)	(3,357)
Other income (expense)	(15)	37
Net loss	$ (7,999)	$ (3,320)
Basic and diluted net loss per share	$ (1.30)	$ (2.15)
Weighted average number of basic and diluted common shares	6,131,821	1,546,839

Consolidated Balance Sheets
(In thousands)

	March 31, 2021	**December 31, 2020**
Assets:		
Cash and cash equivalents	$ 29,637	$ 35,853
Prepaid expenses and other current assets	802	1,122
Property, equipment, other assets and restricted cash	272	279
Right-of-use assets	108	146

License agreement	1,809	1,864
Goodwill	1,034	1,034
Total assets	$ 33,662	$ 40,298
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 3,448	$ 2,843
Current portion of long-term obligations	67	92
Long-term obligations	59	77
Stockholders' equity	30,088	37,286
Total liabilities and stockholders' equity	$ 33,662	$ 40,298

SOURCE: Achieve Life Sciences, Inc.

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