November 12, 2020

Achieve Reports Financial Results for Third Quarter 2020 and Provides Corporate and Cytisinicline Development Update

SEATTLE and VANCOUVER, BC, Nov. 12, 2020 /PRNewswire/ -- 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 third quarter 2020 financial results and provided an update on the cytisinicline clinical development program.

Recent Events & Highlights

- Initiated the Phase 3 ORCA-2 clinical trial evaluating the efficacy and safety of 3 mg cytisinicline dosed 3 times daily compared to placebo in 750 adult smokers at 15 clinical sites in the United States
- Promoted John Bencich to Chief Executive Officer and Dr. Cindy Jacobs to President
- Presented successful results from the RAUORA, head-to-head non-inferiority clinical trial comparing cytisinicline and Chantix® (varenicline), at the Society for Research on Nicotine and Tobacco European (SRNT-E) Annual Meeting
- Presented mechanism of action data comparing 5-HT_3 receptor activity of cytisinicline vs. Chantix at SRNT-E, providing rationale for differentiated side effect profile of smoking cessation treatments
- Announced smoking cessation Key Opinion Leader Virtual Roundtable to be held on November 17, 2020

"With the initiation of the Phase 3 ORCA-2 trial and the breakthrough evidence, both mechanistically and clinically, in support of cytisinicline in comparison to Chantix, the third quarter of 2020 has undeniably been the most pivotal in the history of our company," commented John Bencich, Chief Executive Officer of Achieve. "Our primary focus in the coming months will be enrollment and execution of ORCA-2, while continuing to explore opportunities for commercialization and expansion into new therapeutic indications, digital health technologies, and audiences who may benefit from cytisinicline, specifically, users of vapes or e-cigarettes."

Phase 3 ORCA-2 Trial Initiation

Achieve's first Phase 3 ORCA-2 trial was initiated in October 2020 and will randomize 750 U.S. smokers to one of three study arms to determine the efficacy and safety of cytisinicline administered for either 6 or 12 weeks, compared to placebo. The primary endpoint is biochemically verified continuous abstinence during the last 4 weeks of treatment in the 6 and 12-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.

Management Team Update
In September, the Company announced the promotion of John Bencich to Chief Executive Officer and Dr. Cindy Jacobs to President. Mr. Bencich has been serving as Achieve's Chief Financial and Operating Officer since 2017 and will join the Board of Directors in his role. Dr. Jacobs has been serving as the Chief Medical Officer of Achieve since 2017 and will continue in her role leading the regulatory and clinical development efforts for cytisinicline. Rick Stewart will remain with Achieve as the Executive Chairman of the Board of Directors and Dr. Anthony Clark will remain in his role as Chief Scientific Officer.

RAUORA: Significantly Fewer Adverse Events and Higher Quits Rates for Cytisinicline vs Chantix
Final results from the New Zealand RAUORA Phase 3 non-inferiority clinical trial comparing cytisinicline to varenicline (Chantix) in Māori (indigenous New Zealanders) and whānau (family) of Māori were presented at the SRNT-E Annual Meeting in September 2020. Results showed that cytisinicline met the pre-specified non-inferiority endpoint and was trending towards superiority demonstrating a 4.29% improvement in quit rates in favor of cytisinicline. Subjects in the cytisinicline arm were approximately one and a half times more likely to have quit smoking at 6 months compared to subjects who received varenicline. Importantly, significantly fewer overall adverse events (AEs) were reported in cytisinicline-treated subjects. Of the subjects who experienced AEs (111 in the cytisinicline arm compared to 138 in the varenicline arm), there was significantly less nausea and vivid dreams.

MOA Data Explaining Reduced Nausea and Vomiting with Cytisinicline Presented at SRNT-E
Data presented at the SRNT-E Annual Meeting in September 2020 provides a rationale based on detailed receptor pharmacology to explain why the incidence of nausea and vomiting associated with cytisinicline appears to be consistently lower than that seen with Chantix. The preclinical study, conducted at the University of Cambridge Department of Biochemistry, was designed to examine the in vitro binding characteristics of cytisinicline compared to varenicline at the human 5-HT_3 receptor. The study reported an IC50 of 0.50 mM for cytisinicline and 0.25 μM for varenicline, representing a 2000-greater fold agonist binding affinity to the 5-HT_3 receptor for varenicline compared to cytisinicline.

Virtual Smoking Cessation KOL Roundtable to be Held November 17, 2020
Achieve announced plans to host a virtual roundtable on cytisinicline and smoking cessation on Tuesday, November 17, 2020, at 12:00PM EST. Five esteemed experts in the field of smoking cessation will discuss the ongoing ORCA-2 trial, review recent cytisinicline data, and discuss the importance of smoking cessation in the midst of the COVID-19 pandemic. Visit http://ir.achievelifesciences.com/events-and-webcasts for additional information and click here to register for the event.

Financial Results
As of September 30, 2020, the company's cash, cash equivalents, and restricted cash was $22.4 million. Total operating expenses for the three and nine months ended September 30, 2020 were $3.8 million and $10.0 million, respectively. Total net loss for the three and nine months ended September 30, 2020 was $3.8 million and $10.0 million, respectively.

As of November 12, 2020, Achieve had 3,617,664 shares outstanding.

Conference Call Details
Achieve will host a conference call at 4:30pm Eastern time today, Thursday, November 12, 2020. 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 8047128. 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 U.S. 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.

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.

Media Contact
Glenn Silver
Glenn.Silver@Finnpartners.com
(646) 871-8485

Investor Relations Contact
Jason Wong
jwong@bplifescience.com
(415) 375-3340 ext. 4

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	1,891	1,824	4,535	7,911
General and administrative	1,863	1,893	5,494	5,408
Total operating expenses	3,754	3,717	10,029	13,319
Loss from operations	(3,754)	(3,717)	(10,029)	(13,319)
Other income (expense)	(10)	44	23	118
Net loss	$ (3,764)	$ (3,673)	$ (10,006)	$ (13,201)
Basic and diluted net loss per share	$ (1.14)	$ (9.07)	$ (4.55)	$ (35.96)
Weighted average number of basic and diluted common shares	3,289,252	405,012	2,197,368	367,103

Consolidated Balance Sheets
(In thousands)

	September 30, 2020	December 31, 2019
Assets:		
Cash, cash equivalents, short term investments and restricted cash	$ 22,443	$ 16,714
Prepaid expenses and other current assets	1,669	670
Property, equipment and other assets	358	244
Right-of-use assets	193	329
License agreement	1,920	2,087
Goodwill	1,034	1,034
Total assets	$ 27,617	$ 21,078
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 1,719	$ 2,666
Current portion of long-term obligations	129	203
Long-term obligations	94	159
Stockholders' equity	25,675	18,050
Total liabilities and stockholders' equity	$ 27,617	$ 21,078

View original content to download multimedia:http://www.prnewswire.com/news-releases/achieve-reports-financial-results-for-third-quarter-2020-and-provides-corporate-and-cytisinicline-development-update-301171373.html

SOURCE Achieve Life Sciences, Inc.