November 9, 2021

Achieve Reports Financial Results for Third Quarter 2021 and Provides Update on Cytisinicline Development

SEATTLE, Wash and VANCOUVER, British Columbia, Nov. 09, 2021 (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 third quarter 2021 financial results and provided an update on the cytisinicline clinical development program.

Recent Highlights

- Provided an update on the ORCA-2 Phase 3 clinical trial, including announcing that all subjects have completed the treatment portion of the study and are in follow-up, and that topline data is expected in the first half of 2022
- Discussed ongoing planning activities for ORCA-3, the second Phase 3 clinical trial supporting cytisinicline regulatory submission in the United States, which Achieve anticipates could launch by early 2022
- Announced FDA acceptance of IND application for the evaluation of cytisinicline in nicotine e-cigarette cessation
- Issued two new patents from the United States Patent and Trademark Office covering the novel 3.0 mg TID cytisinicline dosing regimen
- Presented cytisinicline data at the Society for Research on Nicotine & Tobacco Europe (SRNT-E) annual meeting
- Announced expansion of cytisinicline clinical operations team

“It has been another successful quarter as we continue to focus on meeting our key development milestones, specifically, completing the Phase 3 ORCA-2 trial, and preparing for the initiation of two new cytisinicline trials,” commented John Bencich, Chief Executive Office of Achieve. “We are looking forward to an exciting year ahead with the expected ORCA-2 Phase 3 data results, the start of our second Phase 3 study in cigarette smoking cessation and launch of the grant-funded ORCA-V1 trial in e-cigarette cessation.”

Ongoing ORCA-2 Phase 3 Clinical Trial
Achieve provided an update on the cytisinicline development program in adult cigarette

smokers in the United States. The ORCA-2 Phase 3 trial completed enrollment of 810 subjects. To date, all subjects have completed study treatment and are currently in follow-up. The last subject is expected to complete their final visit by the end of 2021, with topline data expected to be announced in the first half of 2022.

Planned ORCA-3 Phase 3 Clinical Trial
Achieve reviewed ORCA-3 planning activities and announced that it has completed selection of a Contract Research Organization (CRO), finalized cytisinicline packaging and drug supply, and is currently undergoing clinical trial site selection. The trial is expected to initiate enrollment of approximately 750 adult cigarette smokers by early 2022.

FDA Acceptance of IND for Study of Cytisinicline in e-Cigarette Cessation
Achieve announced that the U.S. Food and Drug Administration (FDA) has completed their review and accepted an Investigational New Drug (IND) application to investigate cytisinicline as a cessation treatment for nicotine e-cigarette users. 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 (NIDA) of the National Institutes of Health (NIH). 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.

Patents Issued for 3.0 mg TID Dosing Regimen
The U.S. Patent and Trademark Office issued U.S. Patent No. 11,083,715 and U.S. Patent No. 11,083,716 covering the novel 3.0 mg TID cytisinicline dosing regimen. Not including any patent term extensions to which Achieve may be entitled, the newly issued patents will expire in the third quarter of 2040. Upon approval of cytisinicline by the FDA, Achieve anticipates these patents would be included in the FDA's Orange Book, which lists approved drugs and related patent and exclusivity information.

Cytisinicline Data Presented at SRNT-E Annual Meeting
Two cytisinicline data presentations were included in the SRNT-E annual meeting, held in September 2021. An analysis from the ORCA-1 trial found that subjects who previously failed to quit smoking with Chantix® (varenicline) experienced a Week 4 abstinence rate of 51.3% upon treatment with cytisinicline using the three times daily (TID) regimen, compared with 15.8% with placebo ($p= 0.009$). An additional analysis, also from the ORCA-1 trial, found that smokers treated in the study with cytisinicline showed an earlier onset of sustained abstinence compared with placebo. Smokers who received the cytisinicline 3 mg TID had the shortest time to sustained smoking abstinence with a median of only 7 days of treatment compared to 18 days for placebo.

Expanded Clinical Operations Team
Achieve announced the expansion of its clinical operations team to include a Senior Director of Biometrics, Senior Manager of Clinical Trials, and Director of Clinical Operations, to support efforts with the ongoing and planned cytisinicline development program.

Financial Results
As of September 30, 2021, Achieve's cash equivalents, and restricted cash was $33.4 million. Total operating expenses for the three and nine months ended September 30, 2021 were $6.7 million and $26.0 million, respectively. Total net loss for the three and nine months ended September 30, 2021 was $6.7 million and $26.0 million, respectively.

As of November 9, 2021, Achieve had 9,453,542 shares outstanding.

Conference Call Details
Achieve will host a conference call at 4:30pm Eastern time today, Tuesday, November 9, 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 7997636. 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 and commercialization activities, the ability to provide patent protection for Achieve's cytisinicline program, the potential listing of the patents in the FDA's Orange Book, 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.

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,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	4,591	1,891	19,460	4,535
General and administrative	2,102	1,863	6,519	5,494
Total operating expenses	6,693	3,754	25,979	10,029
Loss from operations	(6,693)	(3,754)	(25,979)	(10,029)
Other income (expense)	2	(10)	(22)	23
Net loss	$ (6,691)	$ (3,764)	$ (26,001)	$ (10,006)
Basic and diluted net loss per share	$ (0.71)	$ (1.14)	$ (3.39)	$ (4.55)
Weighted average number of basic and diluted common shares	9,452,238	3,289,252	7,670,383	2,197,368

Consolidated Balance Sheets
(In thousands)

	September 30, 2021	December 31, 2020
Assets:		
Cash and cash equivalents	$ 33,312	$ 35,853
Prepaid expenses and other current assets	1,421	1,122
Property, equipment, other assets and restricted cash	256	279
Right-of-use assets	79	146
License agreement	1,697	1,864
Goodwill	1,034	1,034
Total assets	$ 37,799	$ 40,298
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 3,007	$ 2,843
Current portion of long-term obligations	69	92
Long-term obligations	23	77
Stockholders' equity	34,700	37,286
Total liabilities and stockholders' equity	$ 37,799	$ 40,298

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