March 14, 2019

Achieve Reports Financial Results for Year-End 2018 and Provides Cytisinicline Clinical Development Update

SEATTLE and VANCOUVER, British Columbia, March 14, 2019 /CNW/ -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation, today provided an update on the cytisinicline clinical development program and announced fourth quarter and year-end 2018 financial results.

Recent Highlights

- Completion of enrollment in 254-subject Phase 2b ORCA-1 trial of cytisinicline in U.S. smokers
- Presented final data from cytisinicline Phase 1/2 multi-dose, pharmacokinetic and pharmacodynamics (PK/PD) study at the Society for Research on Nicotine & Tobacco (SRNT) Annual Meeting
- Initiated a trial to assess the maximum tolerated dose, or MTD, for a single administered oral dose of cytisinicline
- Pediatric waiver agreed by the U.S. Food and Drug Administration (FDA)

- Closed registered direct offering for gross proceeds of $5.6 million

Rick Stewart, Chairman and Chief Executive Officer of Achieve Life Sciences commented, "The cytisinicline development program continues to advance rapidly and we are well-poised for continued success in 2019. As demonstrated by the swift enrollment in our Phase 2b trial, new treatments are desperately needed to help the millions of people who desire to quit smoking."

ORCA-1 Phase 2b Trial Fully Enrolled

In February, Achieve announced completion of enrollment of 254 smokers in a Phase 2b trial evaluating cytisinicline in both the 1.5 mg and 3.0 mg doses on a declining titration schedule as well as three times daily dosing, both over 25 days. The primary efficacy endpoint is reduction in the number of cigarettes smoked during treatment with secondary analyses to be conducted on smoking cessation rates, safety, and compliance. ORCA-1 is being conducted at eight centers across the U.S. and results are expected in mid-2019.

PK/PD Study Results Demonstrating Impressive Smoking Cessation Rates

The study evaluated the repeat-dose PK and PD effects of 1.5 mg and 3.0 mg cytisinicline in 26 healthy volunteer smokers when administered over the standard 25-day course of treatment. All subjects had a significant and immediate reduction in cigarettes smoked within 2 days of initiating cytisinicline treatment. By Day 26, subjects had an average 80% reduction in cigarettes smoked, 82% reduction in expired carbon monoxide (CO), and 46% had stopped smoking.

MTD Study Initiation

In March, Achieve initiated a trial to assess the MTD for a single administered oral dose of cytisinicline. This study will be performed in smokers who will receive one single dose of cytisinicline. The dosage of cytisinicline will be increased in separate groups of subjects per dose level until stopping criteria are reached, based on the occurrence of dose-limiting adverse events.

FDA Agrees to Full Waiver for Pediatric Population

FDA confirmed that they are in agreement with Initial Pediatric Study Plan, specifically, providing a full waiver for evaluating cytisinicline in a pediatric population. The reasons for the full waiver were based on the low numbers of children smoking under the age of 12 and the logistical difficulties of recruiting treatment-seeking smokers in the adolescent age group. The agreed Pediatric Study Plan will be included as part of Achieve's future application for marketing approval of cytisinicline.

Completed $5.6M Financing

In October 2018, Achieve announced the closing of a registered direct offering that raised total gross proceeds of $5.6 million and after deducting approximately $0.6 million in placement agent fees and offering expenses, receiving net proceeds of $5.0 million.

Financial Results

As of December 31, 2018, the company's cash, cash equivalents, short-term investments and restricted cash were $14.7 million. Total operating expenses for the fourth quarter and year ended December 31, 2018 were $3.7 million and $12.8 million, respectively. Total net loss for the fourth quarter and year ended December 31, 2018 was $3.6 million and $12.7 million, respectively.

As of March 14, 2019 Achieve had 6,721,200 shares outstanding.

Conference Call Details
Achieve will host a conference call at 4:30 p.m. Eastern time today, Thursday, March 14, 2019. 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 2057479. 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 and is responsible for nearly seven million deaths annually worldwide[1]. It is estimated that 28.7% of cancer deaths in the U.S. are attributable to cigarette smoking[2]. Achieve's focus is to address the global smoking health 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.

As an approved, branded product in Central and Eastern Europe for more than two decades, it is estimated that over 20 million people have used cytisinicline to help combat nicotine addiction.

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 planned cytisinicline clinical development activities, the timing of clinical development activities related to cytisinicline, the potential market size for cytisinicline and the potential benefits of cytisinicline. 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; 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 law.

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[1] World Health Organization. WHO Report on the Global Tobacco Epidemic, 2017. Geneva: World Health Organization, 2017

[2] Annals of Epidemiology , Volume 25 , Issue 3 , 179 - 182.e1

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

	Three months ended December 31,		Twelve months ended December 31,	
	2018	**2017**	**2018**	**2017**
Operating expenses:				
Research and development	2,081	2,153	5,868	3,101
General and administrative	1,628	1,629	6,945	3,531
Total operating expenses	3,709	3,782	12,813	6,632
Loss from operations	(3,709)	(3,782)	(12,813)	(6,632)
Other income (expense)	72	42	126	(7,002)
Net loss before income taxes	$ (3,637)	$ (3,740)	$ (12,687)	$ (13,634)
Recovery of deferred income taxes	—	—	—	3,051
Net loss	$ (3,637)	$ (3,740)	$ (12,687)	$ (10,583)
Basic and diluted net loss per share	$ (0.55)	$ (3.17)	$ (3.61)	$ (22.07)
Weighted average number of basic and diluted common shares	6,659,379	1,179,812	3,510,217	479,442

Consolidated Balance Sheets
(In thousands)

	December 31, 2018	**December 31, 2017**
Assets:		
Cash, cash equivalents, short term investments and restricted cash	$ 14,654	$ 5,556
Prepaid expenses and other current assets	933	402
Property, equipment and other assets	153	368
License agreement	2,310	2,532
Goodwill	1,034	1,034
Total assets	$ 19,084	$ 9,892

Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 3,259	$ 1,986
Current portion of long-term obligations	11	27
Long-term obligations, less current portion	12	—
Stockholders' equity	15,802	7,879
Total liabilities and stockholders' equity	$ 19,084	$ 9,892

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