November 7, 2018

Achieve Reports Financial Results for Third Quarter 2018 and Provides Cytisinicline (Cytisine) Clinical Development Update

SEATTLE and VANCOUVER, British Columbia, Nov. 7, 2018 /PRNewswire/ -- 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 third quarter 2018 financial results.

Recent Highlights

- The United States Adopted Name Council, or USAN, adopted cytisinicline as the nonproprietary (generic) name for the substance also known as cytisine
- Announced initiation of the first trial in the ORCA (***O****ngoing* ***R****esearch of* ***C****ytisinicline for* ***A****ddiction*) Program. This Phase 2b optimization study will evaluate approximately 250 smokers in the U.S.
- Reported results of a clinical study evaluating the effect of food on the bioavailability of a new formulation for cytisinicline
- Closed registered direct offering for gross proceeds of $5.6 million
- Announced positive cytisinicline data published in the International Journal of Drug Policy

Rick Stewart, Chairman and Chief Executive Officer of Achieve Life Sciences commented, "We are pleased with our continued progress made in the third quarter, particularly the initiation of the ORCA-1 trial that will provide critical insights to inform our Phase 3 program expected to initiate in the second-half of 2019."

"Cytisinicline" Designated as New Generic Name for Cytisine

The United States Adopted Names (USAN) Council adopted cytisinicline as the nonproprietary (generic) name in Q3 2018. USAN is responsible for selecting simple, informative, and unique generic drug names. The USAN Council establishes logical nomenclature classifications based on pharmacological and/or chemical relationships.

Initiated Phase 2b "ORCA-1"Optimization Trial

ORCA-1 is the first in Achieve's ORCA (Ongoing Research of Cytisinicline for Addiction) Program that aims to evaluate the effectiveness of cytisinicline for smoking cessation and potentially other indications. This Phase 2b trial will evaluate both the 1.5mg and 3mg doses of cytisinicline on a declining titration schedule over 25 days, as well as three times daily dosing. The trial is randomized and blinded to compare the effectiveness of the cytisinicline doses and schedules to respective placebo groups. 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.

Announced Study Results for New Formulation

The study evaluated the bioavailability of a new formulation of cytisinicline under fed and fasted conditions in 12 healthy volunteer smokers. Results demonstrated bioequivalence when cytisinicline was administered with or without food and that the 3mg dose of this new formulation was well tolerated.

Completed $5.6M Financing

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.

Publication of New Cytisinicline Data in the International Journal of Drug Policy

Results of an observational study comparing the effectiveness of cytisinicline and nicotine replacement therapy (NRT) as an aid to smoking cessation in the Russian Federation determined that smokers in the cytisinicline group were approximately three times more likely to achieve 90-days abstinence compared to those who attempted to quit with NRT (p=0.011). The authors concluded the findings support previous trial evidence indicating that

cytisinicline is superior to NRT for achieving short- and long-term abstinence and should be considered a first-line pharmacologic treatment for smoking cessation.

Financial Results
As of September 30, 2018, the company's cash, cash equivalents, short-term investments and restricted cash were $13.2 million. Total operating expenses for the three and nine months ended September 30, 2018 were $3.3 million and $9.1 million, respectively. Total net loss for the three and nine months ended September 30, 2018 was $3.2 million and $9.1 million, respectively

As of November 7, 2018 Achieve had 6,721,103 shares outstanding.

Conference Call Details
Achieve will host a conference call at 4:30 p.m. Eastern time today, Wednesday, November 7, 2018, to provide an update on the cytisinicline clinical development program and announce third quarter 2018 financial results. To access the webcast, log on to the Investor Relations page of the Achieve website at http://ir.achievelifesciences.com/events-and-webcasts. Alternatively, you may access the live conference call by dialing (877) 472-9809 (U.S. & Canada) or (629) 228-0791 (International) and referencing conference ID 9922429. 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 six million deaths annually worldwide[1]. It is estimated that 28.6% of all 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, 2011, Geneva: World Health Organization, 2011.

[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 September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	1,541	825	3,787	948
General and administrative	1,753	1,550	5,317	1,902
Total operating expenses	3,294	2,375	9,104	2,850
Loss from operations	(3,294)	(2,375)	(9,104)	(2,850)
Other income (expense)	54	(7,025)	54	(7,044)
Net loss before income taxes	$ (3,240)	$ (9,400)	$ (9,050)	$ (9,894)
Recovery of deferred income taxes	—	2,928	—	3,051
Net loss	$ (3,240)	$ (6,472)	$ (9,050)	$ (6,843)
Basic and diluted net loss per share	$ (0.71)	$ (8.96)	$ (3.70)	$ (28.10)
Weighted average number of basic and diluted common shares	4,533,943	722,583	2,448,962	243,510

Consolidated Balance Sheets
(In thousands)

	September 30, 2018	December 31, 2017

Assets:		
Cash, cash equivalents, short term investments and restricted cash	$ 13,195	$ 5,556
Prepaid expenses and other current assets	374	402
Property, equipment and other assets	173	368
License agreement	2,365	2,532
Goodwill	1,034	1,034
Total assets	$ 17,141	$ 9,892
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 2,951	$ 1,986
Current portion of long-tem obligations	11	27
Long-term obligations, less current portion	15	—
Stockholders' equity	14,164	7,879
Total liabilities and stockholders' equity	$ 17,141	$ 9,892

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