March 13, 2020

Achieve Reports Financial Results for Fourth Quarter and Year-End 2019 and Provides Update on Cytisinicline Development Program

SEATTLE and VANCOUVER, British Columbia, March 13, 2020 /CNW/ -- 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 fourth quarter and year-end 2019 financial results and provided an update on the cytisinicline clinical development program.

Recent Highlights

- Completed meeting with the U.S. Food & Drug Administration (FDA) to finalize the Phase 3 cytisinicline clinical development program
- Presented new findings from the Phase 2b ORCA-1 trial evaluating cytisinicline in U.S. smokers at the Society for Research on Nicotine & Tobacco (SRNT) Annual Conference in March 2020
- Established agreement with the FreeMind Group to assist in securing non-dilutive funding to evaluate cytisinicline in vapers and e-cigarette users
- Closed underwritten public offering for gross proceeds of $13.8 million, before underwriting discounts and commissions and offering expenses

"With over 34 million smokers and nearly 11 million vape and e-cigarette users in the United States alone, the nicotine addiction epidemic continues to be a major public health crisis that Achieve is exclusively focused on addressing through the development of cytisinicline," commented Rick Stewart, Chairman and Chief Executive Officer of Achieve. "Our key priorities in the coming months are to initiate the ORCA-2 Phase 3 clinical trial in smokers and secure non-dilutive financing to evaluate cytisinicline specifically in the growing population of vape users."

Completed FDA Meeting

In the fourth quarter of 2019, Achieve received feedback on the Phase 3 clinical trial protocols and the cytisinicline clinical development program. Specifically, the FDA agreed with the overall Phase 3 study designs that anticipate utilizing the simplified cytisinicline dosing schedule of 3.0 mg administered three times daily and the duration of 6 and 12 weeks of treatment. Additionally, the FDA agreed that no further escalation in cytisinicline dosing beyond the 30.0 mg dose was necessary for defining a maximum tolerated dose, which is required for the New Drug Application.

Additional ORCA-1 Results at SRNT Annual Conference

An oral presentation featuring new ORCA-1 Phase 2b trial analyses was presented at the SRNT Annual Meeting in March 2020. In addition to previously reported data indicating a statistically significant improvement in quit rates, new analyses demonstrate cytisinicline biochemical efficacy via measurement of serum cotinine as well as the previous carbon monoxide efficacy. Additionally, further analyses confirm that cytisinicline benefit was observed across all clinical sites, baseline characteristics, and attributes. Thus, regardless of trial site location, patient demographics, smoking history, or prior treatments, all subjects treated with cytisinicline showed similar smoking cessation benefit.

Agreement with the FreeMind Group to secure non-dilutive financing for vaping trials

Achieve retained the FreeMind Group, an international consulting firm dedicated to assisting life science organizations secure non-dilutive funding. Achieve and FreeMind will conduct a strategic assessment of potential non-dilutive funding opportunities from various public and private sources, followed by anticipated grant production and submission, to further the clinical development of cytisinicline in vaping or e-cigarette cessation.

Closed underwritten public offering for gross proceeds of $13.8 million

In December 2019, Achieve announced the closing of an underwritten public offering that raised total gross proceeds of $13.8 million, which includes the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants, prior to deducting underwriting discounts and commissions and offering expenses.

Financial Results
As of December 31, 2019, the company's cash, cash equivalents, and restricted cash was $16.7 million. Total operating expenses for the fourth quarter and year ended December 31, 2019 were $3.2 million and $16.5 million, respectively. Total net loss for the fourth quarter and year ended December 31, 2019 was $3.2 million and $16.4 million, respectively.

As of March 13, 2020 Achieve had 31,352,764 shares outstanding.

Conference Call Details
Achieve will host a conference call at 8:30 a.m. Eastern time today, Friday, March 13, 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 6628874. 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 more than eight 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 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.

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 ability to secure any non-dilutive financing, the timing and nature of cytisinicline clinical development 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; 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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[1] World Health Organization. WHO Report on the Global Tobacco Epidemic, 2019. 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,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	1,763	2,081	9,674	5,868
General and administrative	1,446	1,628	6,854	6,945
Total operating expenses	3,209	3,709	16,528	12,813
Loss from operations	(3,209)	(3,709)	(16,528)	(12,813)
Other income (expense)	15	72	133	126
Net loss	$ (3,194)	$ (3,637)	$ (16,395)	$ (12,687)
Basic and diluted net loss per share	$ (0.30)	$ (0.55)	$ (1.99)	$ (3.61)
Weighted average number of basic and diluted common shares	10,802,186	6,659,379	8,246,400	3,510,217

Consolidated Balance Sheets
(In thousands)

	December 31, 2019	December 31, 2018
Assets:		
Cash, cash equivalents, short term investments and restricted cash	$ 16,714	$ 14,654
Prepaid expenses and other current assets	670	933
Property, equipment and other assets	244	153
Right-of-use assets	329	—
License agreement	2,087	2,310
Goodwill	1,034	1,034
Total assets	$ 21,078	$ 19,084

Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 2,666	$ 3,259
Current portion of long-term obligations	203	11
Long-term obligations	159	12
Stockholders' equity	18,050	15,802
Total liabilities and stockholders' equity	$ 21,078	$ 19,084

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