August 8, 2019

Achieve Reports Financial Results for Second Quarter 2019 and Provides Cytisinicline Clinical Development Update

SEATTLE and VANCOUVER, British Columbia, Aug. 8, 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 second quarter 2019 financial results.

Q2 2019 Highlights

- Reported positive results from the Phase 2b ORCA-1 dose-selection trial evaluating cytisinicline in 254 smokers. Cytisinicline demonstrated a statistically significant improvement in quit rates for a simplified 3.0 mg, three times daily dose. Cytisinicline was well-tolerated with no serious adverse events reported.
- Announced ORCA-1 data has been accepted for an oral presentation at the Society for Research on Nicotine & Tobacco Europe (SRNT-E) 19th Annual Conference to be held in Oslo, Sept. 12-14, 2019
- Patent granted in the U.S. for new cytisinicline succinate salt formulation designed to enhance product stability and long-term potency
- Received $4.2 million in proceeds from exercise of warrants

"It has been an exciting quarter with the release of the positive ORCA-1 Phase 2b trial results that demonstrated impressive smoking cessation efficacy, safety, and cytisinicline treatment adherence," commented Rick Stewart, Chairman and Chief Executive Officer of Achieve. "The data exceeded our expectations and provide a clear path forward for our future Phase 3 program."

ORCA-1 Positive Study Results

The Phase 2b ORCA-1 trial of cytisinicline in U.S. smokers demonstrated a statistically significant improvement in quit rates for the 3.0 mg, three times daily dosing (TID) schedule. In the 3.0 mg TID arm, a 54% abstinence rate at week 4, compared to 16% for placebo ($p < 0.0001$) was observed. Continuous abstinence at weeks 5 through 8 was 30% for cytisinicline compared to 8% for placebo ($p= 0.005$). Adherence to study treatment was 98% in the 3.0 mg TID arm and cytisinicline was well-tolerated with no serious adverse events reported.

Cytisinicline Data Accepted for Presentation

Data from the Phase 2b ORCA-1 trial has been accepted for oral presentation at the SRNT-E Annual Conference, to be held in Oslo, September 12-14, 2019. The abstract "*A Multicenter, Double-blind, Randomized, Placebo-controlled Phase 2b Trial of Cytisinicline in Adult Smokers*" and two, oral presentations will include updated cytisinicline data from the recently completed trial.

Patent Granted in the U.S. for Novel Formulation of Cytisinicline

The U.S. Patent and Trademark Office has granted Achieve a patent on succinate salt of cytisinicline and use thereof. The patent covers a novel salt form of cytisinicline, namely cytisinicline succinate, and pharmaceutical compositions and dosage forms. Achieve has been pursuing cytisinicline succinate salt as a novel new drug product formulation that may further enhance cytisinicline product stability and long-term potency.

Received $4.2 Million from Exercise of Warrants

Achieve announced that it had entered into an agreement with a single investor to exercise outstanding warrants that provided an aggregate of $4.2 million in total proceeds. In exchange for the warrant exercise, Achieve issued to the investor a new warrant, exercisable for six years, to purchase up to 1,200,000 shares of Common Stock at an exercise price of $4.50 per share. The Company filed an S-1 registration statement on July 24, 2019 covering the resale of the shares issuable upon exercise of the new warrant.

Financial Results

As of June 30, 2019, the company's cash, cash equivalents, and restricted cash was $10.5 million. Total operating expenses for the three and six months ended June 30, 2019 were

$3.7 million and $9.6 million, respectively. Total net loss for the three and six months ended June 30, 2019 was $3.6 million and $9.5 million, respectively.

As of August 8, 2019 Achieve had 8,097,763 shares outstanding.

Conference Call Details
Achieve will host a conference call at 4:30 p.m. Eastern time today, Thursday, August 8, 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 6587726. 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, expectations from current data, expectations regarding when trial data may be reported, 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.

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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 June 30,		Three months ended June 30,	
	2019	**2017**	**2019**	**2018**
Operating expenses:				
Research and development	2,032	1,045	6,087	2,246
General and administrative	1,630	1,751	3,515	3,564
Total operating expenses	3,662	2,796	9,602	5,810
Loss from operations	(3,662)	(2,796)	(9,602)	(5,810)
Other income (expense)	38	8	74	-
Net loss	$ (3,624)	$ (2,788)	$ (9,528)	$ (5,810)
Basic and diluted net loss per share	$ (0.50)	$ (1.82)	$ (1.37)	$ (4.18)
Weighted average number of basic and diluted common shares	7,189,672	1,529,532	6,956,722	1,389,209

Consolidated Balance Sheets
(In thousands)

	June 30, 2019	**December 31, 2018**
Assets:		
Cash, cash equivalents, short term investments and restricted cash	$ 10,496	$ 14,654
Prepaid expenses and other current assets	356	933
Property, equipment and other assets	256	153
Operating lease right-of-use assets	414	—
License agreement	2,199	2,310
Goodwill	1,034	1,034
Total assets	$ 14,755	$ 19,084

Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 2,796	$ 3,259
Current portion of long-term obligations	16	11
Current portion of long-term lease liability	176	—
Long-term obligations	20	12
Long-term lease liability	243	—
Stockholders' equity	11,504	15,802
Total liabilities and stockholders' equity	$ 14,755	$ 19,084

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