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Achieve Reports Financial Results for First Quarter 2018

SEATTLE and VANCOUVER, British Columbia, May 9, 2018 /PRNewswire/ -- Achieve Life Sciences, Inc. (NASDAQ: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisine for smoking cessation, today announced first quarter 2018 financial results and recent highlights.

First-Quarter 2018 Highlights

- Announced preliminary results from a Phase I/II clinical study evaluating pharmacokinetic (PK) and pharmacodynamics (PD) effects of 1.5mg and 3mg cytisine

doses demonstrating an average 58% abstinence rate in healthy volunteer smokers at the end of treatment period
- Expanded partnership with the University of Bristol for next generation cytisine-based therapies across multiple therapeutic categories
- Participated in symposia at the Society for Research on Nicotine and Tobacco (SRNT) and at the World Conference on Tobacco or Health (WCTOH)
- Announced new patent granted on novel formulation of cytisine

"Clinical study results continue to reinforce the established benefit of cytisine as a potential new treatment option for smoking cessation in the U.S.," commented Rick Stewart, Chairman and Chief Executive Officer of Achieve Life Sciences. "The upcoming meeting with the FDA will aid in finalizing our Phase 3 trial planning and we look forward to the initiation of our Phase 3 clinical trial program later this year."

University of Bristol Expanded Partnership
In January, Achieve announced an amendment to their Technology License Agreement with the University of Bristol. Achieve has been granted exclusive rights for all human medicinal uses of cytisine derivatives created under the License Agreement across all therapeutic categories. Under the amended collaboration agreement, studies will be conducted to generate and evaluate semi-synthetic cytisine derivatives for potential use in multiple indications across addiction and neurological disorders.

PK/PD Study Results
In February, Achieve announced preliminary results from a study evaluating repeat-dose PK and PD effects of 1.5mg and 3mg cytisine when administered over the standard 25-day course of treatment in 24 healthy volunteer smokers, aged 18-65 years. The PK results indicated expected increases in plasma concentration with higher doses of cytisine. Smokers in the study were not required to have a designated or predetermined quit date, however, 58% of the subjects in the trial achieved biochemically verified smoking abstinence by day 26. Subjects who did not achieve abstinence had a significant reduction in the number of daily cigarettes smoked by the end of treatment. Cytisine was well-tolerated with no serious adverse events reported. The adverse events observed were mostly mild with transient headaches as the most commonly reported event with a slight increase in transient headaches in the 3 mg versus 1.5 mg cytisine dose level. The study is continuing enrollment for subjects aged >65 years.

New Cytisine Patent Granted
In March, a new patent on cytisine succinate salt was granted to Achieve by the UK Intellectual Property Office. Achieve has been pursuing cytisine succinate salt as a novel new drug product formulation that may further enhance cytisine product stability and long term potency. The Company expects to file the patent globally under the Patent Cooperation Treaty, or PCT, in the coming months.

Financial Results
As of March 31, 2018, the company's cash, cash equivalents, short-term investments and restricted cash was $4.4 million. Total operating expenses for the first quarter of 2018 was $3.0 million. Net loss for the first quarter of 2018 was $3.0 million.

As of March 31, 2018 Achieve had 12,747,932 shares outstanding.

About Achieve & Cytisine
Achieve's focus is to address the global smoking health epidemic through the development

and commercialization of cytisine. 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].

Cytisine is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. Two prior, large-scale Phase 3 clinical studies of cytisine, with favorable outcomes, have been successfully completed in over 2,000 patients. The TASC trial was a 740 patient, double-blind, placebo controlled trial conceived by Professor Robert West at University College London and funded by the U.K. National Prevention Research Initiative. The CASCAID trial was a 1,310 patient, single-blind, non-inferiority trial comparing cytisine to nicotine replacement therapy (NRT). The CASCAID trial was conceived by Dr. Natalie Walker, National Institute for Health Innovation, University of Auckland and funded by the Health Research Council of New Zealand. Both trials were published in the New England Journal of Medicine.

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 of clinical development of cytisine, and the potential benefits of cytisine. 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 cytisine 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 cytisine; the risk that cytisine 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 March 31,	
	2018	2017
Operating expenses:		
Research and development	1,201	61
General and administrative	1,813	260
Total operating expenses	3,014	321
Loss from operations	(3,014)	(321)
Other income (expense)	(8)	(8)
Net loss before income taxes	$ (3,022)	$ (329)
Recovery of deferred income taxes	-	124
Net loss	$ (3,022)	$ (205)
Basic and diluted net loss per share	$ (0.24)	$ (9.66)
Weighted average number of basic and diluted common shares	12,431,488	21,230

Consolidated Balance Sheets
(In thousands)

	March 31, 2018	December 31, 2017
Assets:		
Cash, cash equivalents, short term investments and restricted cash	$ 4,437	$ 5,556
Prepaid expenses and other current assets	359	402
Property, equipment and other assets	153	368
License agreement	2,477	2,532
Goodwill	1,034	1,034
Total assets	$ 8,460	$ 9,892
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 2,318	$ 1,986
Current portion of long-tem obligations	-	27
Stockholders' equity	6,142	7,879
Total liabilities and stockholders' equity	$ 8,460	$ 9,892

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