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Achieve Announces Recent Highlights and Reports Year-End 2017 Financial Results

BOTHELL, Wash. and VANCOUVER, British Columbia, March 1, 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 highlighted recent accomplishments and announced fourth quarter and year-end 2017 financial results.

Recent Highlights

- Announced preliminary results from clinical study evaluating pharmacokinetic (PK) and pharmacodynamics (PD) effects of 1.5mg and 3mg cytisine demonstrating an overall 58% abstinence rate in healthy volunteer smokers
- Expanded partnership with the University of Bristol for next generation cytisine-based therapies across multiple therapeutic categories
- Announced final results of clinical study demonstrating similar bioavailability of cytisine in fed and fasted subjects
- Entered into an exclusive long-term supply agreement with Sopharma AD for clinical and commercial supply of cytisine

"Significant advances in the cytisine development program have been achieved in the short time since the completion of our merger," commented Rick Stewart, Chairman and Chief Executive Officer of Achieve Life Sciences. "Clinical progress with cytisine continues to provide evidence supporting the outcome of two, previously conducted Phase 3 trials and the in-market cytisine experience over the last 20 years in Eastern Europe. We look forward to continued collaboration with the smoking cessation community, regulators, and researchers, as we move towards our expected Phase 3 trial initiation later this year."

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.

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.

Fed/Fasted Study Results

In November, 2017, the Company announced final results of a study on the effect of food on the bioavailability of cytisine. The study evaluated the bioavailability of a single 3 mg cytisine dose under fed and fasted conditions in 24 healthy volunteer subjects. Study results demonstrated overall bioequivalence when cytisine was administered with or without food. Total excretion levels of cytisine also remained equivalent in both the fed and fasted states.

Sopharma Agreement

In October 2017, Achieve entered into an exclusive supply agreement with Bulgarian-based Sopharma AD for the manufacture of cytisine's active pharmaceutical ingredient (API) and finished tablets. Achieve will have full access to the cytisine supply chain and Sopharma will manufacture sufficient cytisine to meet specified forecasted demand of cytisine in the

Achieve territories. The exclusive license agreement provides supply of cytisine to Achieve for up to 20 years. Sopharma has over 20 years of experience producing cytisine through its commercialization efforts in Central and Eastern Europe. It is estimated that over 20 million people have used cytisine to treat nicotine addiction.

Financial Results
As of December 31, 2017, the company's cash, cash equivalents, short-term investments and restricted cash was $5.6 million. Total operating expenses for the fourth quarter and year ended December 31, 2017 were $3.8 million and $6.6 million, respectively. Net loss for the fourth quarter and year ended December 31, 2017 was $3.7 million and $10.6 million, respectively.

As of March 1, 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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Consolidated Statements of Loss

(In thousands, except per share and share data)

	Three months ended December 31		Twelve months ended December 31,	
	2017	**2016**	**2017**	**2016**
Operating expenses:				
Research and development	2,153	80	3,101	286
General and administrative	1,629	529	3,531	1,428
Total operating expenses	3,782	609	6,632	1,714
Loss from operations	(3,782)	(609)	(6,632)	(1,714)
Other income (expense)	42	(4)	(7,002)	(24)
Net loss before income taxes	$ (3,740)	$ (613)	$ (13,634)	$ (1,738)
Recovery of deferred income taxes	—	127	3,051	504
Net loss	$ (3,740)	$ (486)	$ (10,583)	$ (1,234)
Basic and diluted net loss per share	$ (0.32)	$ (22.89)	$ (2.21)	$ (58.13)
Weighted average number of basic and diluted common shares	11,798,116	21,230	4,794,421	21,230

Consolidated Balance Sheets

(In thousands)

	December 31, 2017	December 31, 2016
Assets:		
Cash, cash equivalents, short term investments and restricted cash	$ 5,556	$ 15
Amounts receivable	9	—
Prepaid expenses and other current assets	393	3
Property, equipment and other assets	368	—
License agreement	2,532	2,755
Goodwill	1,034	1,034
Total assets	$ 9,892	$ 3,807

Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 1,986	$ 2,244
Stockholder loans with related parties	—	829
Current portion of long-term obligations	27	—
Deferred tax liability	—	124
Stockholders' equity	7,879	610
Total liabilities and stockholders' equity	$ 9,892	$ 3,807

[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

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