August 8, 2018

Achieve Reports Financial Results for Second Quarter 2018 and Provides Cytisine Clinical Development Update

SEATTLE and VANCOUVER, British Columbia, Aug. 8, 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 provided an update on the cytisine clinical development program and announced second quarter 2018 financial results.

Recent Achieve Highlights

- Announced plans to initiate a Phase 2b optimization trial in the fourth quarter of 2018 following a meeting conducted with the United States (U.S.) Food and Drug Administration (FDA)
- Closed underwritten public offering for gross proceeds of $13.8 million
- Reported positive data demonstrating no clinically significant drug-drug interactions from a series of drug metabolism, drug interaction, and transporter studies evaluating cytisine
- Announced publication of data on next-generation cytisine molecules
- Announced new patent granted on novel formulation of cytisine

Rick Stewart, Chairman and Chief Executive Officer of Achieve Life Sciences commented, "We have made tremendous progress over the past few months on the cytisine development program, particularly the outcome of our discussions with the FDA that have provided us with clarity on our overall development strategy."

FDA Meeting Outcome and Phase 2b Optimization Trial
Recent discussions with the FDA concluded that the Company may proceed with the Phase 3 program, however they recommended consideration of alternative dosing strategies that may enhance patient compliance. Consistent with this advice, Achieve plans to conduct a 250-patient Phase 2b trial in the U.S. that will evaluate overall treatment efficacy, safety, and compliance profiles of various cytisine dosing regimens compared to placebo.

Completed $13.8M Financing
Achieve announced the closing of an underwritten public offering of units for 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 estimated offering expenses.

Positive Data Demonstrating No Clinically Significant Drug-to-Drug Interaction Studies
A series of drug metabolism, drug-to-drug interaction, and transporter studies demonstrated that cytisine has no clinically significant interaction with any of the hepatic enzymes commonly responsible for drug metabolism nor clinically significant interaction with drug transporters. This suggests that cytisine may be administered with other medications without the need to modify the dose of the co-administered drug.

Data on Next-Generation Cytisine Molecules Published
The Company announced that cytisine data, generated in collaboration with the University of Bristol, was published in Chem. Data show that via the use of C-H activation chemistry, the cytisine molecule can be modified in a highly targeted and selective manner to generate a new class of cytisine derivatives that may enable future development of product candidates for smoking cessation and other indications.

Patent Granted on Cytisine Succinate Salt
Achieve announced in May that the UK Intellectual Property Office granted a patent (no. 2550241) on cytisine succinate salt. The Company 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 has filed the patent globally under the Patent Cooperation Treaty, or PCT, in July.

Financial Results
As of June 30, 2018, the company's cash, cash equivalents, short-term investments and

restricted cash was $15.3 million. Total operating expenses and net loss for the three and six months ended June 30, 2018 was $2.8 million and $5.8 million, respectively.

As of August 8, 2018 Achieve had 4,551,005 shares outstanding.

Conference Call Details
Achieve will host a conference call at 4:30 p.m. Eastern time today, Wednesday August 8, 2018, to provide an update on the cytisine clinical development program and announce second quarter 2018 financial results. A live event will be available on the Investor Relations section of the Achieve website at http://ir.achievelifesciences.com/events-and-webcasts. Alternatively, you may access the live conference call at (877) 472-9809 (U.S. & Canada) or (629) 228-0791 (International – additional toll-free international dial-in numbers are also available on the event page) and referencing conference ID 1468638. A webcast replay will be available on Achieve's website for 90 days after the call.

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 planned cytisine clinical development activities, the potential market size for 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.

Achieve Contact
Jason Wong
jwong@bplifescience.com
(415) 375-3340 ext. 4

[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 June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	1,045	62	2,246	123
General and administrative	1,751	93	3,564	352
Total operating expenses	2,796	155	5,810	475
Loss from operations	(2,796)	(155)	(5,810)	(475)
Other income (expense)	8	(11)	—	(20)
Net loss before income taxes	$ (2,788)	$ (166)	$ (5,810)	$ (495)
Recovery of deferred income taxes	—	—	—	124
Net loss	$ (2,788)	$ (166)	$ (5,810)	$ (371)
Basic and diluted net loss per share	$ (1.82)	$ (78.66)	$ (4.18)	$ (175.22)
Weighted average number of basic and diluted common shares	1,529,532	2,123	1,389,209	2,123

Consolidated Balance Sheets
(In thousands)

	June 30, 2018	December 31, 2017
Assets:		
Cash, cash equivalents, short term investments and restricted cash	$ 15,330	$ 5,556
Prepaid expenses and other current assets	292	402
Property, equipment and other assets	143	368
License agreement	2,421	2,532
Goodwill	1,034	1,034
Total assets	$ 19,220	$ 9,892

Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 2,749	$ 1,986
Current portion of long-tem obligations	11	27
Long-term obligations, less current portion	18	—
Stockholders' equity	16,442	7,879
Total liabilities and stockholders' equity	$ 19,220	$ 9,892

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