UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 20, 2018

ACHIEVE LIFE SCIENCES, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**033-80623**	**95-4343413**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1001 W. Broadway, Suite 400 **Vancouver, BC** **(Address of Principal Executive Offices)**	**V6H 4B1** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (604)736-3678

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

A copy of Achieve Life Sciences, Inc.'s (the "Company") press release announcing preliminary data from the cytisine Phase I/II multi-dose, pharmacokinetic and pharmacodynamics clinical study and a copy of the Company's related corporate presentation are furnished as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K.

The information in this Item 7.01 of Current Report on Form8-K, as well as Exhibits 99.1 and 99.2, shall not be treated as "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Title or Description
99.1	Press Release issued by Achieve Life Sciences, Inc. dated February 20, 2018
99.2	Achieve Life Sciences, Inc. Corporate Presentation

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ACHIEVE LIFE SCIENCES, INC.

Date: February 20, 2018

/s/ John Bencich
John Bencich
Chief Financial and Operating Officer

Exhibit 99.1

Achieve Announces Preliminary Data from Cytisine Phase I/II Multi-Dose, Pharmacokinetic and Pharmacodynamics (PK/PD) Clinical Study

BOTHELL, Washington and VANCOUVER, British Columbia, February 20, 2018 — 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 preliminary data from their Phase I/II multi-dose, pharmacokinetic and pharmacodynamics (PK/PD) clinical study of cytisine.

The study, initiated in October 2017, evaluated the repeat-dose PK and PD effects of 1.5mg and 3mg cytisine in 24 healthy volunteer smokers aged 18-65 years when administered over the standard 25-day course of treatment. The PK results indicated expected increases in plasma concentration between the standard and higher doses of cytisine with no evidence of drug accumulation. Smokers in the study were not required to have a designated or predetermined quit date, however, 58% of the subjects overall in the trial achieved biochemically verified smoking abstinence at day 26. Half (6/12) of the subjects on the 1.5mg arm and 67% (8/12) of the subjects on the 3.0mg arm achieved abstinence on day 26. Subjects who did not achieve abstinence had a significant reduction in number of daily cigarettes smoked by the end of treatment.

Cytisine was well-tolerated and reported adverse events were mostly mild and short-lived. Transient headache was the most commonly reported event, but was not treatment-limiting. No adverse events were severe, serious, or led to withdrawal from the study. Study results will be included in a clinical symposium on cytisine at the Society for Research on Nicotine and Tobacco (SRNT) Annual Meeting in Baltimore on Friday, February 23rd.

“The abstinence rates observed with cytisine are particularly impressive given the short 25-day treatment period. In addition, subjects did not commit to quitting and received only minimal behavioral support. Setting an actual quit date and receiving enhanced behavioral support are key factors to improve smoking cessation outcomes,” said Dr. Cindy Jacobs, Executive Vice President and Chief Medical Officer at Achieve. “We are encouraged by these results that further support our Phase 3 program that we expect to initiate mid-2018.”

Cytisine is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is an established smoking cessation treatment that has been available in Central and Eastern Europe for more than 20 years. Achieve is collaborating with leading opinion leaders and researchers to facilitate cytisine availability globally as well as in the United States. Achieve expects to initiate the cytisine Phase 3 development program in mid-2018 required for FDA approval of cytisine in the United States.

About Achieve and 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].

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, the 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 the final Proxy Statement/Prospectus/Information Statement filed pursuant to Rule 424(b)(3) in connection with Achieve's recent merger, and 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

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(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

- Achieve Life Sciences -
Committed to advancing cytisine as a smoking cessation aid to address the global tobacco addiction epidemic

Forward Looking Statements

This presentation contains forward-looking statements, including, but not limited to, statements regarding the timing of planned clinical development activities of cytisine; the projected path toward potential regulatory approval; the safety, efficacy and commercial potential of cytisine; the potential market for cytisine; the benefits of cytisine relative to competitors; the anticipated benefits of cytisine; plans, objectives, expectations and intentions with respect to future operations. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Achieve Life Science, Inc. (Achieve) may not actually achieve its plans or product development goals in a timely manner, if at all, or otherwise carry out the intentions or meet the 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, general business and economic conditions; the need for and ability to obtain additional financing; the risk that cytisine may not demonstrate the hypothesized or expected benefits; 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; other risks associated with the process of developing, obtaining regulatory approval for and commercializing drug candidates that are safe and effective for use as human therapeutics; 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 the final Proxy Statement/Prospectus/Information Statement filed pursuant to Rule 424(b)(3) in connection with Achieve's recent merger, and 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.

Phase I/II
Repeat Dose PK/PD Preliminary Study Results

February 2018

Cytisine Overview

- Cytisine is a plant-based alkaloid with high affinity and specificity for neuronal nicotinic (α4β2) receptors.
- Established smoking cessation treatment that has been available in Central and Eastern Europe since the 1960's; Estimated 20 million smokers have been treated with cytisine.
- Two Phase 3 trials were conducted and published in NEJM in 2011 & 2014 demonstrating efficacy and safety of cytisine as an aid to smoking cessation.
- Achieve Life Sciences, in collaboration with research partners, is pursuing clinical development efforts required for FDA and other regulatory approvals.

Phase I/II Repeat Dose PK/PD Clinical Study of Cytisine

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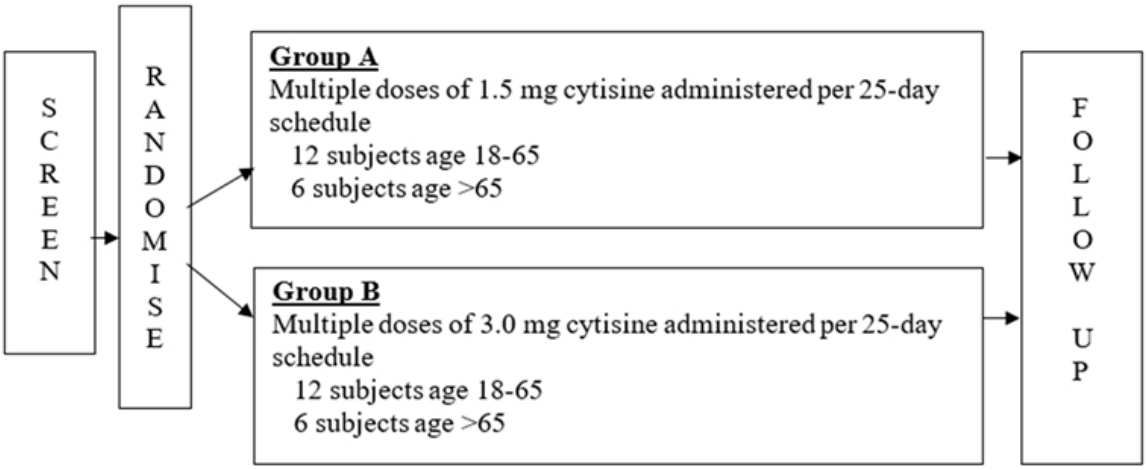
Objective: Evaluate PK profile and PD effect of 1.5mg and 3mg cytisine when administered as the standard 25-day schedule

Population: Healthy, volunteer smokers (≥10 cigarettes/day and expired air CO > 11 ppm), and interested in smoking cessation (no quit date set or required)



Cytisine Dosing Schedule
1.5 mg Standard Dose vs. 3 mg Dose

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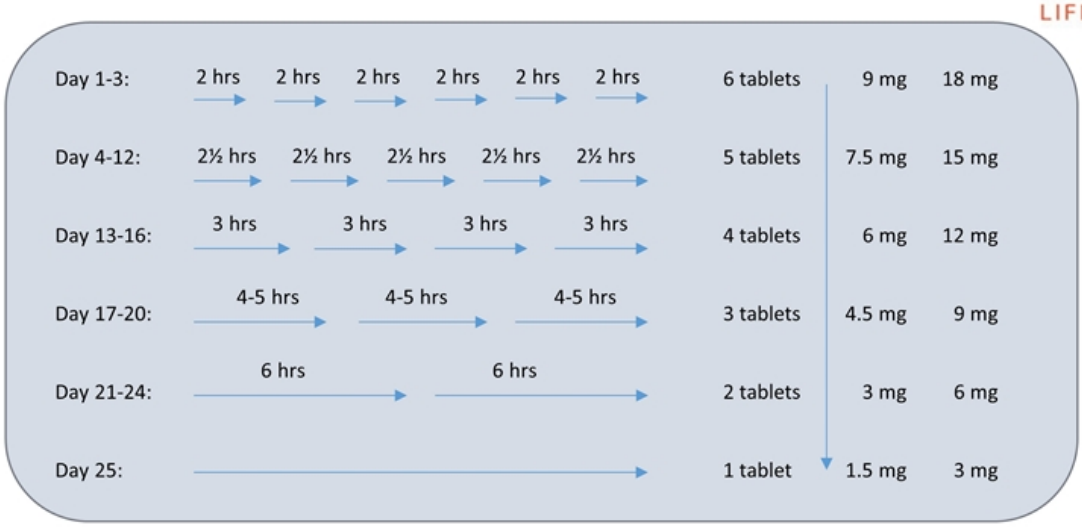


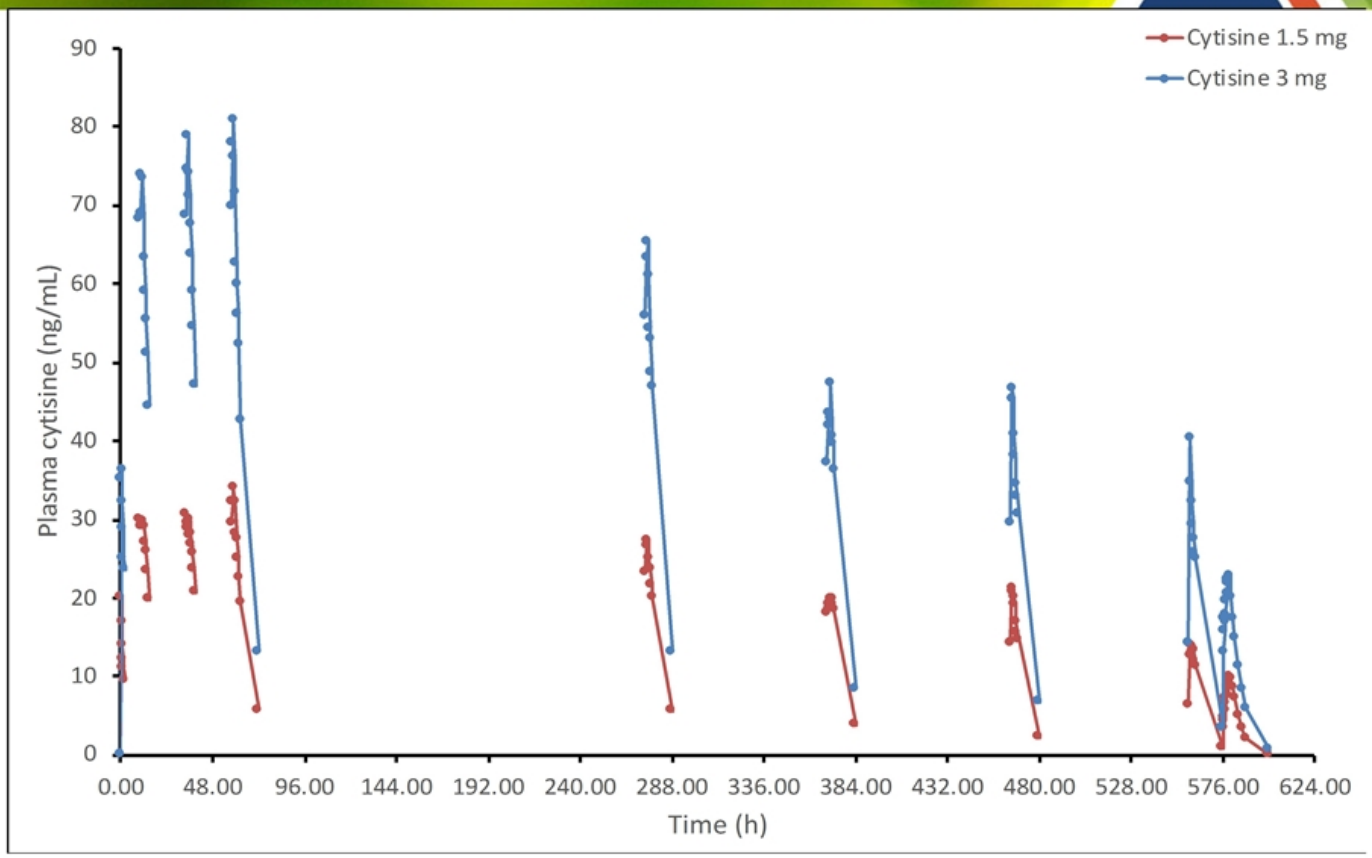
Plasma samples to characterise C_{max}

- Day 1 at first dose; Day 1, Day 2 & Day 3 at dose 6
- Day 12 dose 5; Day 16 dose 4; Day 20 dose 3; Day 24 dose 2
- Day 25 dose 1

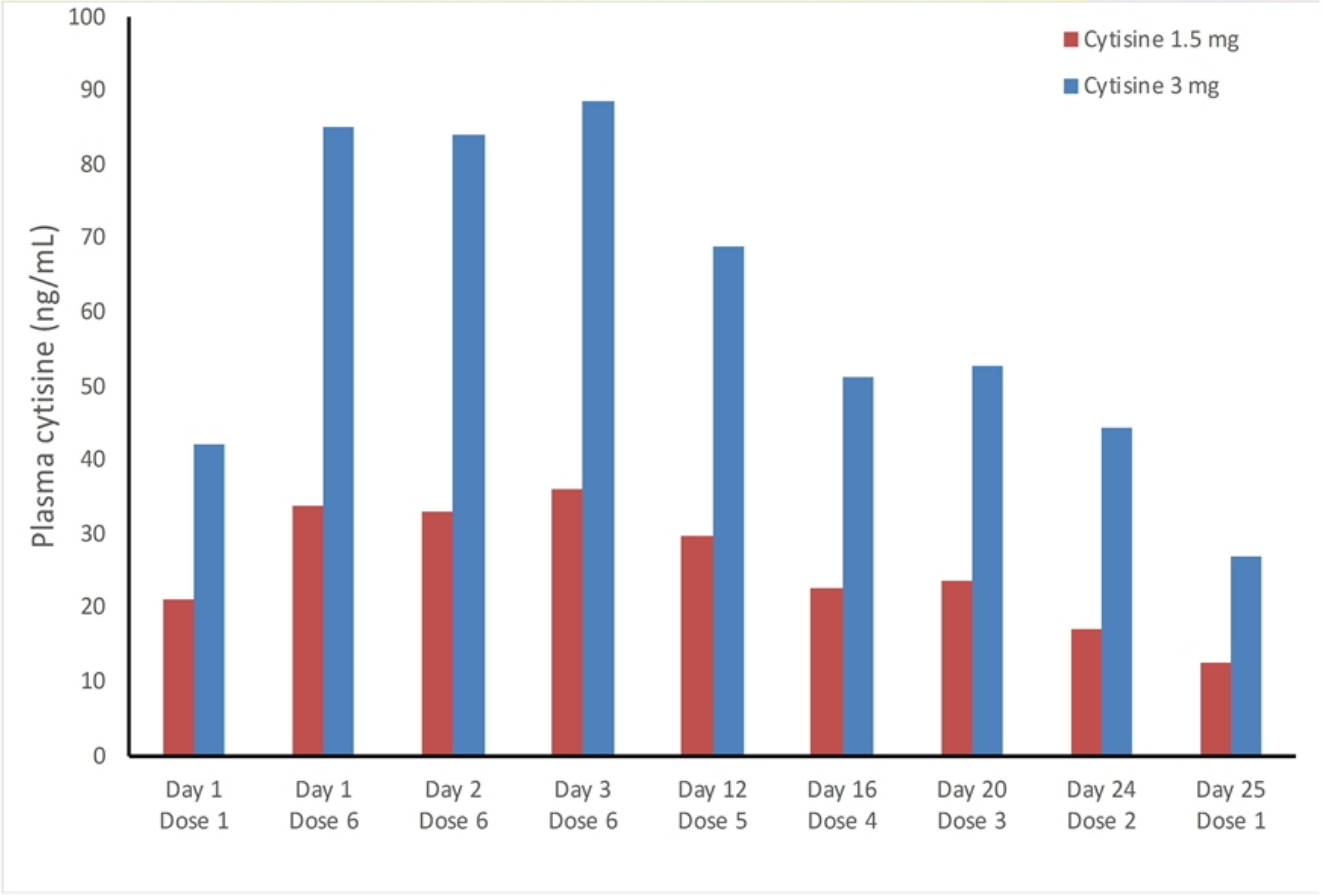
Demographics

Characteristic	1.5 mg Cytisine (N=12)	3.0 mg Cytisine (N=12)	Overall (N=24)
Caucasian Other	12 (100%)	11(92%) 1 (8%)	23 (96%) 1 (4%)
Female Male	4 (33%) 8 (67%)	5 (42%) 7 (58%)	9 (37%) 15 (63%)
Age (yrs) Mean (SD) Median (Min, Max)	 35.0 (9.4) 33.5 (20, 50)	 38.8 (10.3) 38.0 (24, 59)	 36.9 (9.8) 35.0 (20, 59)
Expired air CO (ppm) Mean (SD) Median (Min, Max)	 19.9 (7.3) 18.5 (12, 37)	 21.3 (6.6) 20.0 (13, 38)	 20.6 (6.9) 20.0 (12, 38)
Number of cigarettes smoked in past 24 hrs. Mean (SD) Median (Min, Max)	 16.3 (2.6) 15.0 (12, 20)	 18.6 (2.2) 20.0 (15, 20)	 17.5 (2.7) 18.0 (12, 20)

PK Profile: Predictable plasma concentration



PK Results (Cmax)



Repeat Dose PK/PD Study Results: Significant Efficacy Signals Observed

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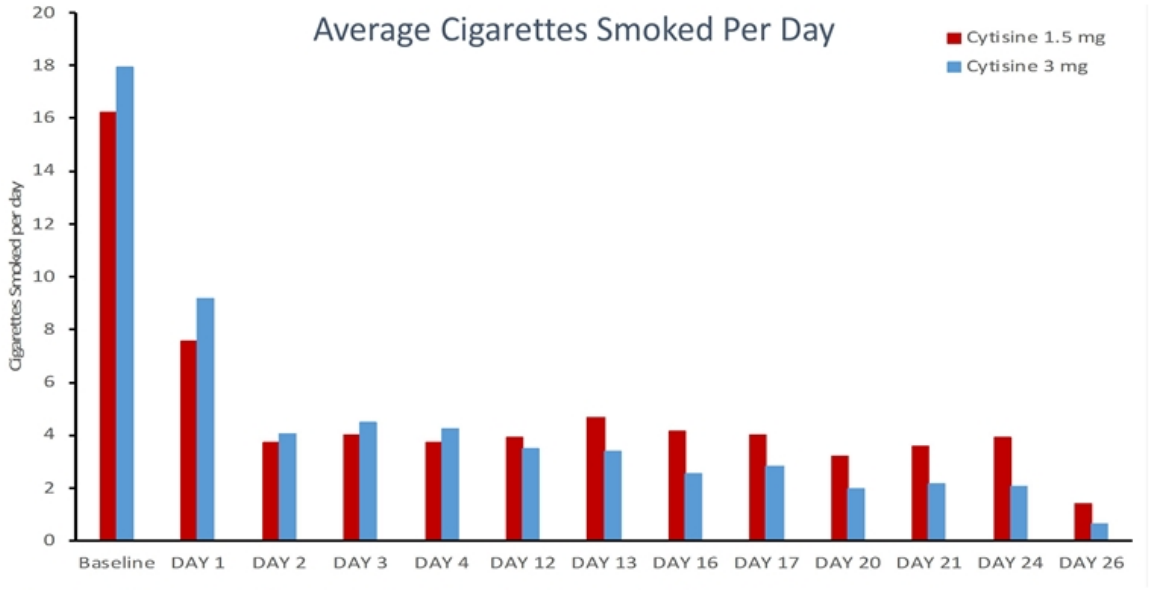
Abstinence Rates (Biochemically verified) on Day 26	
Cytisine 1.5 mg	50% (6/12)
Cytisine 3 mg	67% (8/12)
Overall	58% (14/24)



Note: Results from subjects in the age 18 to 65 cohort. The age >65 cohort is still ongoing.

Adverse Events*: Number (%) of Subjects

Preferred Term	1.5 mg Cytisine (N=12)	3.0 mg Cytisine (N=12)	Overall (N=24)
Any	8 (67%)	9 (75%)	17 (71%)
Headache	4 (33%)	7 (58%)	11 (46%)
Chest discomfort	0	2 (17%)	2 (8%)
Nausea	0	2 (17%)	2 (8%)

* Any other AEs occurred in only 1 subject overall

Conclusions

- PK & PD data confirm previously demonstrated cytisine effects
- Abstinence rate (biochemically confirmed) was 58% overall by end of 25-day treatment
- Both doses of cytisine were well-tolerated with mainly mild AEs
- Two randomized, controlled Phase 3 trials required for FDA approval and expected to commence in mid-2018