

October 26, 2017



Achieve Announces Exclusive, Long-term Manufacturing Agreement with Sopharma for Clinical and Commercial Supply of Cytisine

BOTHELL, Wash. and VANCOUVER, British Columbia, Oct. 26, 2017 /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 it has entered into an exclusive supply agreement with Sopharma AD (BSE: 3JR, WSE: SPH) for the manufacture of cytisine active pharmaceutical ingredient (API) and finished tablets.



Under the terms of the agreement, Sopharma agrees to produce cGMP-grade cytosine for Achieve's use in the development and commercialization of cytosine. Sopharma has over 20 years of experience producing cytosine through its commercialization efforts in Central and Eastern Europe. In addition, Achieve will have full access to the cytosine supply chain and Sopharma will manufacture sufficient cytosine to meet specified forecasted demand of cytosine in the Achieve territories. The exclusive license agreement provides supply of cytosine to Achieve for up to 20 years.

"This agreement with Sopharma reinforces our commitment and ability to bring cytosine forward as a new treatment option to help the millions of smokers who are battling nicotine and tobacco addiction," said Rick Stewart, Chairman and CEO of Achieve. "We look forward to our continued partnership with Sopharma as we work together to address this global public health epidemic that claims the lives of more than six million people annually worldwide."

Achieve recently announced completion of enrollment in a clinical study evaluating the effect of food on the bioavailability of 3mg cytosine and commencement of a multi-dose, PK/PD clinical study. Data from both trials will be used to further inform the Phase 3 clinical program, which is expected to begin enrollment in the United States in mid-2018.

About Cytosine

Achieve's focus is to address the global smoking health epidemic through the development and commercialization of cytosine. Tobacco use is currently the leading cause of preventable death and is responsible for nearly six million deaths annually worldwide¹. It is estimated that 28.6% of all cancer deaths in the U.S. are attributable to cigarette smoking².

Cytosine 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 approved and

marketed in Central and Eastern Europe for over 20 years. It is estimated that over 20 million people have used cytisine to help combat nicotine addiction, including over 2,000 patients in investigator-conducted, Phase 3 clinical trials in Europe and New Zealand.

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. Learn more at www.achievelifesciences.com

About Sopharma AD

Sopharma is a Bulgarian based EU pharmaceutical producer with over 80 years tradition in the field. The company is a strong regional player and a responsible partner to the Bulgarian government in the health care sector supporting the entire healthcare system and the hospital sector in particular. The product portfolio expands to over 200 products in all main therapeutic areas known in more than 40 markets on 5 continents. Sopharma has over 30 subsidiaries in the production, distribution and retail sectors in more than 10 countries. In H1 2017 the Group reached almost 250 million EUR sales revenues with EBITDA growth of 37.3% and net profit growth of 14.2% compared to H1 2016. The Group continues to grow and establish itself as a preferred partner in the region. Learn more at www.sopharmagroup.com

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.

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¹World Health Organization. WHO Report on the Global Tobacco Epidemic, 2011, Geneva: World Health Organization, 2011.

²Annals of Epidemiology , Volume 25 , Issue 3 , 179 - 182.e1

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