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## **Achieve Life Science and OncoGenex Pharmaceuticals Announce Strategic Collaboration with the National Institutes of Health to Advance the Development of Cytisine for Smoking Cessation**

### **Ongoing IND-enabling Non-clinical Program to Support the Use of Cytisine in Smoking Cessation**

### **Multiple Key Cytisine Development and Regulatory Milestones Expected in 2017**

MILL VALLEY, Calif., BOTHELL, Wash. and VANCOUVER, British Columbia, March 1, 2017 /CNW/ -- Achieve Life Science, Inc. (Achieve) and OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) (OncoGenex) today announced a strategic collaboration with the National Center for Complementary and Integrative Health (NCCIH) at the National Institutes of Health (NIH) to conduct non-clinical studies in support of an overall clinical development plan for cytisine as a smoking cessation treatment.

As part of the collaboration, Achieve is providing cytisine to the NIH to conduct a series of non-clinical studies required by the U.S. Food and Drug Administration (FDA) to support the submission of an Investigational New Drug (IND) application. The collaboration commenced in March 2015 and results of the initial study are expected in the second-quarter of 2017.

"Given the burden of smoking-related illnesses and existing preliminary data that indicates efficacy and safety, we consider cytisine to be a potential drug of public health importance," said David Shurtleff, Ph.D., NCCIH Deputy Director. "We are hopeful that our research collaborations will lead to more smoking cessation aids and reduce the number of lives lost due to tobacco smoking and nicotine addiction."

According to the U.S. Surgeon General's 2014 report<sup>1</sup> "The Health Consequences of Smoking - 50 years of Progress", there are more than 16 million Americans living with a disease caused by smoking and it is responsible for more than 480,000 deaths per year. The Report states that productivity losses from premature death exceed \$150 billion per year and the annual costs of direct medical care of adults attributable to smoking are estimated to be over \$130 billion.

Rick Stewart, Chairman and Chief Executive Officer of Achieve commented, "We are delighted that the NIH has provided assistance to Achieve in updating the non-clinical package for cytisine. We intend to file the IND in the second half of 2017. Phase 1 studies are expected to commence later in the year and a Phase 3 trial is expected to start in the first half of 2018."

Two recent, large-scale 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 in December 2011 and December 2014, respectively.

Achieve announced in January 2017 that it had entered into a definitive merger agreement with OncoGenex Pharmaceuticals, Inc.

### **References:**

1. <https://www.surgeongeneral.gov/library/reports/50-years-of-progress/exec-summary.pdf>

### **About Achieve and Cytisine**

Achieve is developing cytisine as a smoking cessation aid. 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 approved and marketed in Central and Eastern Europe for more than 15 years. It is estimated that over 20 million people have used cytisine to help combat nicotine addiction, including approximately 2,000 patients in clinical trials conducted in Europe and New Zealand. Achieve's focus is to address the global smoking health epidemic, which is currently the leading cause of preventable death and is responsible for nearly six million people losing their lives annually worldwide. Discussions have been held with FDA and a European regulatory agency to determine the clinical and regulatory pathway towards making cytisine widely

available.

### **Important Additional Information about the Proposed Merger**

This communication is being made in respect of the proposed merger involving OncoGenex Pharmaceuticals, Inc. and Achieve Life Science, Inc. OncoGenex intends to file a registration statement on Form S-4 with the SEC, which will contain a joint proxy statement/prospectus and other relevant materials, and plans to file with the SEC other documents regarding the proposed transaction. The final joint proxy statement/prospectus will be sent to the stockholders of OncoGenex and Achieve. The joint proxy statement/prospectus will contain information about OncoGenex, Achieve, the proposed merger and related matters. STOCKHOLDERS ARE URGED TO READ THE JOINT PROXY STATEMENT/PROSPECTUS (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS) AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE, AS THEY WILL CONTAIN IMPORTANT INFORMATION THAT STOCKHOLDERS SHOULD CONSIDER BEFORE MAKING A DECISION ABOUT THE MERGER AND RELATED MATTERS. In addition to receiving the joint proxy statement/prospectus and proxy card by mail, stockholders will also be able to obtain the joint proxy statement/prospectus, as well as other filings containing information about OncoGenex, without charge, from the SEC's website (<http://www.sec.gov>) or, without charge, by directing a written request to: OncoGenex Pharmaceuticals, Inc., 19820 North Creek Parkway, Suite 201, Bothell, WA 98011, Attention: Investor Relations or to Achieve Life Science, Inc., 30 Sunnyside Avenue, Mill Valley, CA 94941, Attention: Rick Stewart.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities in connection with the proposed merger shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

### **Participants in Solicitation**

OncoGenex and its executive officers and directors may be deemed to be participants in the solicitation of proxies from OncoGenex's stockholders with respect to the matters relating to the proposed merger. Achieve and its officers and directors may also be deemed a participant in such solicitation. Information regarding OncoGenex's executive officers and directors is available in OncoGenex's proxy statement on Schedule 14A, filed with the SEC on April 21, 2016. Information regarding any interest that OncoGenex, Achieve or any of the executive officers or directors of OncoGenex or Achieve may have in the transaction with Achieve will be set forth in the joint proxy statement/prospectus that OncoGenex intends to file with the SEC in connection with its stockholder vote on matters relating to the proposed merger. Stockholders will be able to obtain this information by reading the joint proxy statement/prospectus when it becomes available.

### **About OncoGenex**

OncoGenex is a biopharmaceutical company committed to the development and commercialization of new therapies that address treatment resistance in cancer patients. The company's product candidate, apatersen (OGX-427), is designed to inhibit production of Hsp27, disable cancer cells' defenses and overcome treatment resistance. Hsp27 is an intracellular protein that protects cancer cells by helping them survive, leading to resistance and more aggressive cancer phenotypes. Both the potential single-agent activity and synergistic activity of apatersen with cancer treatments may increase the overall benefit of existing therapies and augment the durability of treatment outcomes, which could lead to increased patient survival. More information is available at [www.OncoGenex.com](http://www.OncoGenex.com) and at the company's Twitter account: [https://twitter.com/OncoGenex\\_IR](https://twitter.com/OncoGenex_IR).

### **OncoGenex' 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 proposed merger with Achieve Life Science; the non-clinical and clinical development of cytisine, including the timing of expected development milestones; the potential benefits of cytisine and apatersen; and the potential market opportunity and size for cytisine. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. OncoGenex and/or Achieve may not actually achieve the proposed merger, or any 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, the failure of the OncoGenex or Achieve stockholders to approve the transaction; the failure of either party to meet the closing conditions of the transaction; delays in completing the transaction and the risk that the transaction may not be completed at all; the failure to realize the anticipated benefits from the transaction or delay in realization thereof; the success of the combined businesses; operating costs and business disruption during the pendency of and following the proposed merger; the risk that product candidates will not receive regulatory approval or be successfully commercialized; the risk that new developments in the rapidly evolving cancer therapy landscape require changes in business strategy or clinical development plans; the risk that product candidates may not demonstrate the hypothesized or expected benefits; general business and economic conditions; and the other factors described in our risk factors set forth in OncoGenex's filings with the Securities and Exchange Commission from time to time, including its Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. OncoGenex 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.

To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/achieve-life-science-and-oncogenex-pharmaceuticals-announce-strategic-collaboration-with-the-national-institutes-of-health-to-advance-the-development-of-cytisine-for-smoking-cessation-300415203.html>

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