

Achieve Life Sciences initiates cytisine clinical development programme

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Achieve Life Sciences, Inc., a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisine for smoking cessation, announced initiation of the cytisine clinical development programme.

Cytisine 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 over 2,000 patients in investigator-conducted, phase 3 clinical trials in Europe and New Zealand.

In preparation to initiate a pivotal phase 3 trial in the United States, Achieve expects to conduct the clinical studies in 2017: Evaluation of the effect of food on the bioavailability of cytisine – enrollment has started, the first subjects have been dosed and data analysis expected to be completed in Q4 2017; Assessment of repeat-dose pharmacokinetic (PK) parameters and pharmacodynamics (PD) – expected to commence in Q4 2017.

“In the last month Achieve has announced the closing of our merger with OncoGenex and subsequent listing on NASDAQ, the FDA acceptance of Achieve’s cytisine IND, and now the initiation of the cytisine clinical development programme,” said Rick Stewart, Chairman and CEO of Achieve. “We are focused on achieving our milestones with our primary goal of initiating a US pivotal phase 3 trial next year.”

Achieve’s focus is to address the global smoking health epidemic through the development and commercialization of cytisine. Smoking is currently the leading cause of preventable death and is responsible for nearly six million people losing their lives annually worldwide.

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. Two prior, large-scale phase 3 clinical studies of cytisine, with favorable outcomes, have been successfully completed in over 2,000 patients.