

**TABEX SHOWN TO BE A HIGHLY COST EFFECTIVE TREATMENT FOR
SMOKING CESSATION - STUDY PUBLISHED IN PEER REVIEWED JOURNAL,
*NICOTINE AND TOBACCO RESEARCH***

Cost-effective treatment has potential to advance smoking cessation globally in developed and developing markets

Based on results from successful TASC 740-patient pivotal trial recently published in the *New England Journal of Medicine*

Wilmington, Delaware & London, January 9th, 2012 – Achieve Life Sciences (“Achieve”) a clinical stage biopharmaceutical company with a focus on smoking cessation, today announced the results of a cost effectiveness study published in the journal, *Nicotine and Tobacco Research*. These data are based on the results of the Tabex Smoking Cessation (“TASC”) 740-patient pivotal trial, which were published in the *New England Journal of Medicine* on September 29, 2011.

The primary endpoint of the TASC trial was the Russell Standard criteria for smoking cessation measured at 12 months from the end of treatment. Quit rates were confirmed by exhaled carbon monoxide levels. The trial showed a strongly statistically significant result with a Risk Ratio of 3.4 ($p < 0.001$) indicating that smokers treated with Tabex were 3.4 times more likely to quit than those on placebo. The pivotal trial met all its primary and secondary efficacy endpoints.

Rick Stewart, Chairman of Achieve, said “*We were delighted with the highly positive and statistically significant results from the TASC trial, especially as they compare most favourably with the current market-leading prescription smoking cessation treatments. Moreover, extensive evaluation of the Tabex safety database shows no evidence of significant neuropsychiatric or behavioural side-effects as seen with some currently marketed smoking cessation drugs. These positive data confirm the outcomes from previous clinical trials and corroborate the in-market experience of Tabex with the approximately 20 million patients who have received the drug to date. The addition of behavioural support in future clinical trials should further enhance Tabex’s efficacy and safety profile, which we expect will accelerate our route to approval for Tabex.*”

According to a new study published today in the peer review journal, *Nicotine and Tobacco Research*, health care systems globally could gain substantial cost savings by offering an alternative to nicotine replacement products, varenicline and bupropion. According to the study, Tabex (cytisine), which has been used in Central and Eastern European countries for many years, would increase each year of life at a cost of about \$300, compared to current National Health Service (United Kingdom) medicines’ cost which in the region of \$3,000¹.

The study conducted at the Cancer Research UK Health Behaviour Research Centre at University College London by John Stapleton and Robert West, describes a standard methodology and gives tables to enable the immediate calculation of the cost-effectiveness of all effective smoking cessation interventions. It follows recent publication of a trial showing Tabex to be effective in helping people stop smoking².

Professor Robert West, Department of Epidemiology and Public Health at University College London and Principal Investigator on the TASC trial, concluded, *“With more than a billion smokers worldwide and lung cancer still as one of the top killers, the results of the TASC trial and these cost effectiveness data show that not only is Tabex comparable with market leading smoking cessation treatments, but that its cost effectiveness has the capacity to save millions of lives globally”*

John Stapleton who led the cost-effectiveness study said: *“The new Cancer Research UK report shows that more than 40% of cancers are avoidable, and that smoking is still by far the leading cause of these preventable cancers”*³. *“Smoking related diseases remain the single biggest killer globally, the TASC trial and these new cost effectiveness results show that Tabex has a greater potential than existing treatments to save millions of lives globally.*

About Tabex

Tabex has been marketed in Central and Eastern Europe for many years by Sopharma as a comparatively safe and effective treatment for smoking cessation. Over 20 million patients have been treated and the latest Periodic Safety Update Reports (PSUR) submitted to the European Medicines Evaluation Agency (EMA) was based on approaching 8 million cases. Numerous Tabex clinical studies have demonstrated positive efficacy and safety. There have been over 7,000 subjects in clinical trials to date. The TASC study was the first major study to be performed to Good Clinical Practice (GCP). The adverse effects associated with Tabex treatment were generally mild and self-limiting; the benefit-risk for Tabex treatment was excellent.

About Achieve

Achieve Life Sciences is a Delaware company dedicated to seeking regulatory approvals for Tabex in the US, EU and Japan as well as in developing countries.

About Sopharma

Sopharma is the largest Bulgarian pharmaceutical company currently selling its products in 30+ countries with Group annual turnover of €300 M. The largest export markets are Russia, Ukraine, Kazakhstan and Poland. The company has developed and manufactures more than 190 pharmaceutical Rx and OTC products in various therapy areas. Sopharma is the manufacturer and marketing authorization holder for Tabex® in a number of countries in Central and Eastern Europe. Sopharma is currently the main partner of Achieve for the global development and commercialization of Tabex®. More information is available on www.sopharma.bg

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¹ Stapleton JA, West R. A direct method and ICER tables for the cost-effectiveness of smoking cessation interventions in general populations: application to a new cytosine trial and other examples. *Nicotine & Tobacco Research* 2011 online Dec 7 2011

² West R, Zatonski W, Cedzynska M, Lewandowska D, Pazik J, Aveyard P, Stapleton JA. Randomised placebo-controlled trial of cytosine for smoking cessation. *NEJM* 2011; 365(13): 1193-1200.

³ Parkin DH, Boyd L, Walker LC.. The Fraction of Cancer Attributable to Lifestyle and Environmental Factors in the UK in 2010. *Brit. Journal of Cancer* 2011; 105: S77 – S81.