Achieve Life Sciences announces TASC ("TAbex® Smoking Cessation") pivotal trial meets all primary and secondary endpoints with statistically significant quit rates at 1 year

- Strong 1 year quit rate result with Odds Ratio of 3.7 ($p<0.001$)
- Efficacy compared to placebo equivalent to leading prescription smoking cessation treatments
- Results published in the New England Journal of Medicine
- Cost-effective treatment with potential to advance smoking cessation globally
- Strong safety and side-effect profile with no neuropsychiatric issues

Wilmington, Delaware & London, 29th September 2011 – Achieve Life Sciences ("Achieve") a clinical stage biopharmaceutical company with a focus on smoking cessation today reported positive, statistically significant top-line results from the 740 patient double-blind placebo controlled TASC pivotal trial for Tabex. The pivotal trial met all its primary and secondary efficacy endpoints.

The primary endpoint was based on the Russell Standard criteria for 12 months of smoking cessation from the end of treatment. Quit rates were confirmed by exhaled carbon monoxide levels. The 12-month quit rate for Tabex was 8.4% compared to 2.4% for subjects on placebo ($p<0.001$). The Odds Ratio was 3.7 indicating that smokers treated with Tabex were 3.7 times more likely to quit than those on placebo.

The TASC trial was investigator led and conducted with 740 heavy smokers in Poland. Behavioural support and the number of follow-up sessions was minimised to simulate as far as possible a typical clinical environment. The treatment dosing period was 25 days, according to the current approved regimen for Tabex.

The TASC trial was funded by the National Preventative Research Institute (NPRI), including contributions from the British Heart Foundation, the Department of Health and Cancer Research UK. The Principal Investigator was Robert West (Professor of Health Psychology, University College London). It was conducted in Poland under the direction of Witold Zatonski (Professor of Epidemiology at Marie Sklodowska - Curie Memorial Cancer Center in Warsaw).

The results of the clinical trial are published online today in the *New England Journal of Medicine*.

Rick Stewart Chairman and Chief Executive Officer of Achieve said "We are delighted by these very positive results. They confirm the outcomes from previous clinical trials and in-market experience of Tabex. The efficacy rates from the TASC trial compare favourably with the current market-leading prescription smoking cessation treatments. The addition of behavioural support in future clinical trials should further enhance efficacy. Extensive evaluation of the Tabex safety database shows no evidence of significant neuropsychiatric or behavioural side-effects. We believe these new data will accelerate our route to approval for Tabex".

Professor Robert West from the department of Epidemiology and Public Health at University College London who led the study team said: "*With more than a billion smokers worldwide and lung cancer still as one of the top killers, we're extremely encouraged that the benefits of Tabex are comparable with those of market leading smoking cessation treatments, but at a fraction of the cost. We recognise that stopping smoking can be extremely difficult and we hope that by using cytisine as a substitute for*

nicotine, the results of this trial could help transform the health of nations around the globe by offering a practical option even for the poorest smokers."

Jean King, Cancer Research UK's director of tobacco control, said: "It is great news that smokers around the world may have access to a new way to help them beat their addiction. When so many smokers are trying so hard to give up it is ridiculous that tobacco companies are still able to market their deadly products in ways that draw young people into smoking. We hope that cytisine will help low and middle-income countries meet their obligations to help treat nicotine dependence under the World Health Organisation's treaty on tobacco."

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) was based on approaching 4 million patients. 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.

Achieve has licensed global rights to Tabex (excluding existing Sopharma territories) and is developing a patent-protected Tabex product in major developed markets including the US, EU and Japan. Partnering activities for China, India and other developing markets are in progress.

Dr Anthony Clarke (Chief Scientific Officer) said "There is an urgent need for alternative cost-effective prescription smoking cessation treatments. The World Health Organisation estimates that there are over 1.3 billion smokers worldwide, with current smoking-related mortality of over 5 million per year. It also estimates that there will be 1 billion deaths from smoking related diseases this century. We believe Tabex represents a unique opportunity to bring an effective and affordable prescription treatment to market in the West and in the developing world."

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

About Tabex
Tabex is a tablet formulation containing the naturally-occuring alkaloid cytisine. New patent-protected forms are currently in development.

About Sopharma
Sopharma is the leading Bulgarian specialty pharmaceutical company focused on the manufacture and supply of branded and generic drugs in Bulgaria, Russia and other Eastern European countries. Sopharma has a strong history of growth in key markets such as Europe, Asia, Africa and North America . Sopharma has a long history of product origination incluidng Carsil®, Tempalgin®, and Broncholitin®. The demand for Tabex®, Nivalin®, Tribestan®etc. continues to increase in major markets. 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

About NPRI

The National Prevention Research Initiative (NPRI) is a partnership of public and charity sector organisations in the UK. The Funding Partners relevant to this award are: Medical Research Council; British Heart Foundation; Cancer Research UK; Chief Scientist Office of the Scottish Government Health Directorate; Department of Health; Diabetes UK; Economic and Social Research Council; Health and Social Care Research and Development Office for Northern Ireland; The Stroke Association; and the Welsh Assembly Government:

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