

CAMBRIDGE, England, October 15, 2013 /PRNewswire/ --

Acacia Pharma, a pharmaceutical company specialising in the development of drugs for supportive care, announces positive results from its Phase II study of APD515 for the treatment of xerostomia (dry mouth) in advanced cancer patients. The study showed that APD515 significantly reduced the symptoms of dry mouth (the primary endpoint) compared to placebo. APD515 is an optimised oromucosal (liquid) formulation of a currently marketed muscarinic agonist for the completely new, patent-protected use of treatment of xerostomia.

Dr Julian Gilbert, Acacia Pharma's CEO commented, "We are delighted with these results. Dry mouth is a common and distressing issue in advanced cancer patients that is significantly under-recognised. It is associated with a wide range of oral and systemic complications and can contribute to a greatly reduced quality of life. Our market research indicates that a locally delivered, liquid formulation of a suitable salivary stimulant would be of major benefit to many cancer sufferers, and these data indicate that APD515 should meet this profile."

The randomised, double-blind, placebo-controlled, cross-over trial was conducted in 11 centres in the UK and Denmark, and enrolled 32 patients with advanced cancer and a persistently dry mouth. Patients received a week of APD515 treatment and a week of placebo, in a randomly assigned order, with a week's washout in between. Patients graded their symptoms before and after treatment and were asked to record which treatment week they preferred. Patients' unstimulated salivary flow was measured before and after each treatment period.

The study met its primary endpoint of a significant improvement in the subjective scoring of mouth dryness after one week of treatment with APD515 compared to placebo. Subjective scoring was done on a standard 100mm visual analogue scale, where 0 represented no dryness at all and 100 the worst dryness possible. The average score for mouth dryness was 26.01 after treatment with APD515 and 43.52 after placebo ($p=0.0005$). Other subjective scores, for oral comfort, difficulty speaking and difficulty swallowing, all showed a significant improvement for APD515 over placebo. The overall number of adverse events was low, with no significant difference between APD515 and placebo.

The study also assessed whether the blinded treatment had made patients' symptoms better, worse or unchanged. There was a highly significant difference in favour of APD515, with 17 out of 27 patients judging that their dry mouth had improved after APD515, compared to only seven after placebo. When asked for their treatment preference on a blinded basis at the end of the study, 19 subjects preferred APD515 and only one preferred the placebo.

Dr Gabriel Fox, Acacia Pharma's Chief Medical Officer, added: "This was a robust trial, whose cross-over design allowed us to compare the effects of APD515 and placebo in the same patient. The study has shown an unequivocal benefit for APD515 in advanced cancer patients suffering with a dry mouth. APD515 is the first product opportunity to be developed in this hitherto poorly managed patient group."

Initially, Acacia Pharma intends to develop APD515 in advanced cancer patients, up to 80% of whom suffer from some degree of xerostomia, either as a direct result of their disease or as a consequence of their chemotherapy or other medicines they are taking. APD515 also has the potential to be developed for other xerostomic patient populations. The company will be optimising the formulation and presentation in preparation for Phase III testing in an advanced cancer population.

Xerostomia usually results from reduced salivary flow or altered salivary composition and is common in advanced cancer patients, in the elderly, in people taking a wide range of common medications and in conditions such as Sjögren's syndrome.

About Acacia Pharma

Acacia Pharma (<http://www.acaciapharma.com>) is a pharmaceutical company focused on cancer supportive care, a rapidly developing commercial opportunity. The growth in the cancer supportive care market has been driven by the increasing incidence of cancer, the expansion of effective cancer therapies and the desire to improve both the effectiveness of treatment and the quality of life of cancer patients.

Acacia Pharma has generated a pipeline of product opportunities addressing a range of supportive care indications such as nausea & vomiting, xerostomia (dry mouth) and cachexia (muscle wasting) using a commercially driven approach to product discovery based on known

drugs. This strategy leads to product opportunities with a higher probability of success and enables rapid clinical proof-of concept. In addition, Acacia Pharma's products are expected to reach the market quickly given that they are based on the novel use of well-characterised pharmaceuticals.

Acacia Pharma is led by an experienced management team who have already successfully built and exited a number of life sciences companies. Management, Gilde Healthcare, Lundbeckfond Ventures, Novo A/S and Fidelity Biosciences are the Company's key shareholders. Acacia Pharma is based in Cambridge, UK.

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