EudraCT Clinical Trial Results: Primary Endpoint (Safety and Toxicity)

EudraCT number	2014-004388-20
Protocol number	CRUKD/15/004
Protocol title	A Cancer Research UK randomised, double-blind, placebo-controlled Phase IIa trial of AMG 319 given orally as a neoadjuvant therapy in patients with human papillomavirus (HPV) positive and negative head and neck squamous cell carcinoma (HNSCC)
Sponsor	Cancer Research UK, Centre for Drug Development 407 St John Street, London, United Kingdom, EC1V 4AD
End of Trial date	03 May 2018

For the purpose of posting clinical trial results for the Cancer Research UK clinical trial CRUKD/15/004 to the European Clinical Trials Database (EudraCT), the following text summarising the statistical safety and toxicity data from the trial has been extracted from the approved Clinical Study Report (Version 1.0, dated 09 April 2019):

Primary endpoint: Safety and Toxicity

A statistical analysis was performed of the treatment related adverse events (AEs) experienced between treatment arms. Where there appeared to be differences, Fisher's exact test was used to produce p values for specific AEs. Treatment with AMG 319 was found to be associated with an increased incidence of treatment related diarrhoea ($p<0.01$), rash maculo-papular ($p=0.02$) and influenza-like illness ($p=0.03$).

A statistical analysis was also performed of the AEs experienced between treatment arms. Where there appeared to be differences, Fisher's exact test was used to produce p values for specific AEs. Treatment with AMG 319 was associated with an increased incidence of toxicities of Grade 3 or 4 compared to patients receiving placebo (Fisher's exact test, $p=0.05$). Diarrhoea was found to be more common among patients receiving AMG 319 (Fisher's exact test, $p=0.02$), and more AMG 319 patients experienced Grade 3 or greater diarrhoea (23.8% AMG 319 versus 0% placebo). Rash maculo-papular was also more common in patients who received AMG 319 (Fisher's exact test, $p=0.02$) as were toxicities of influenza-like illness ($p<0.01$); all of the AEs of influenza-like illness observed were of lower grades (Grades 1 to 2). Finally, toxicities of ALT increased of any grade ($p=0.07$) were found to be more common among patients who received AMG 319.