

AstraZeneca Head and Neck Cancer Trials

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ASTRAZENECA HEAD AND NECK CANCER TRIALS

Following the recent update on clinicaltrials.gov, AstraZeneca confirms that the US FDA has placed a partial clinical hold on the enrolment of new patients with head and neck squamous cell carcinoma (HNSCC) in clinical trials of durvalumab as monotherapy and in combination with tremelimumab or other potential medicines. All trials are continuing with existing patients.

The partial clinical hold on new patient enrolment relates only to head and neck cancer. Trials for durvalumab in different cancer types, as monotherapy or in combination with tremelimumab or other potential medicines, are progressing as planned, with pivotal data in lung cancer anticipated in the first half of 2017.

The FDA's decision follows voluntary action by AstraZeneca to pause enrolment of new HNSCC patients while a detailed analysis is conducted of adverse events related to bleeding that were observed as part of routine safety monitoring of the Phase III KESTREL and EAGLE trials. Bleeding is a known complication in treatments of head and neck cancers primarily due to the nature of the underlying disease, the proximity of tumours to major blood vessels and use of prior cancer therapies, which may involve surgery and radiation.

AstraZeneca has submitted its analysis of the observed bleeding events to the FDA for review and is working closely with the Agency, providing the required information to resume new patient enrolment as soon as possible.

About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit www.astrazeneca.com and follow us on Twitter @AstraZeneca.

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