

ASTRAZENECA PLC

Form 6-K

November 22, 2016

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of

the Securities Exchange Act of 1934

For the month of November 2016

Commission File Number: 001-11960

AstraZeneca PLC

1 Francis Crick Avenue

Cambridge Biomedical Campus

Cambridge CB2 0AA

United Kingdom

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes ☐ No ☒

If "Yes" is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-_____

AstraZeneca PLC

INDEX TO EXHIBITS

1. AZ head and neck cancer trials resume enrolment dated 22nd November 2016

22 November 2016, 07:00

ASTRAZENECA HEAD AND NECK CANCER TRIALS

RESUME NEW PATIENT ENROLMENT AS FDA LIFTS

PARTIAL CLINICAL HOLD

AstraZeneca today announced that the US FDA has lifted the partial clinical hold on the enrolment of new patients with head and neck squamous cell carcinoma (HNSCC) for clinical trials of durvalumab as monotherapy and in combination with tremelimumab or other potential medicines.

The Phase III KESTREL trial has already re-opened for new patient enrolment at some clinical study sites and the EAGLE trial is expected to resume recruitment shortly, without amendments to either protocol. AstraZeneca will progressively resume enrolment for all HNSCC trials across the participating sites in the US and globally, subject to national health authority and ethics committee approval where required. The status of active recruitment will be

reflected on clinicaltrials.gov in the coming days.

The partial clinical hold on new patient enrolment was communicated on 27 October, after preliminary findings from ongoing clinical trials related specifically to head and neck cancer. The FDA lifted the partial clinical hold following a review of the comprehensive analysis provided by AstraZeneca of bleeding events that were observed as part of the routine safety monitoring of the Phase III KESTREL and EAGLE trials.

Monitoring of safety signals is an integral part of the development process for new medicines. 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.

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.

Media Enquiries

Esra Erkal-Paler	UK/Global	+44 203 749 5638
Neil Burrows	UK/Global	+44 203 749 5637
Vanessa Rhodes	UK/Global	+44 203 749 5736
Karen Birmingham	UK/Global	+44 203 749 5634
Rob Skelding	UK/Global	+44 203 749 5821
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677

Investor Relations

Thomas Kudsk Larsen		+44 203 749 5712
Craig Marks	Finance, Fixed Income, M&A	+44 7881 615 764
Henry Wheeler	Oncology	+44 203 749 5797
Mitchell Chan	Oncology	+1 240 477 3771
Lindsey Trickett	Cardiovascular & Metabolic Diseases	+1 240 543 7970
Nick Stone	Respiratory	+44 203 749 5716
Christer Gruvris	Autoimmunity, neuroscience & infection	+44 203 749 5711

US toll free

+1 866 381 7277

Adrian Kemp

Company Secretary, AstraZeneca PLC

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 22 November 2016 By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary