ASTRAZENECA PLC
Form 6-K
September 07, 2017

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 September 2017

Commission File Number: 001-11960

AstraZeneca PLC

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

7 September 2017 12:30 BST

CELGENE AND ASTRAZENECA PROVIDE UPDATE
ON THE FUSION CLINICAL TRIAL PROGRAMME

AstraZeneca and MedImmune, its global biologics research and development arm, have been informed by partner Celgene that the US Food and Drug Administration (FDA) has placed a partial clinical hold on five trials and a full clinical hold on one trial in the Celgene FUSION programme. The trials are testing Imfinzi (durvalumab), an anti-PD-L1 agent, in combination with immunomodulatory agents, with or without chemotherapy, in blood cancers such as multiple myeloma, chronic lymphocytic leukaemia and lymphoma.

The decision by the FDA was based on risks identified in other trials for an anti-PD-1 agent, pembrolizumab, in patients with multiple myeloma in combination with immunomodulatory agents. No imbalance has been observed in the FUSION programme; however, the clinical holds allow for additional information to be collected to further understand the risk benefit profile of the programme. The FDA has taken similar action with other combination trials in patients with multiple myeloma.

Patients enrolled in the trials on partial clinical hold who are receiving clinical benefit from treatment may remain on treatment. Patients enrolled in the trial on full clinical hold will be discontinued from treatment. No new patients will be enrolled into the listed trials.

Other trials with Imfinzi in haematological malignancies and other tumour types continue unchanged.

The trials placed on partial clinical hold are:

MEDI4736-MM-001: A Phase Ib multicenter, open-label study to determine the recommended dose and regimen of durvalumab either as monotherapy or in combination with pomalidomide with or without low-dose dexamethasone in patients with relapsed and refractory multiple myeloma
MEDI4736-MM-003: A Phase II, multicenter, open-label study to determine the safety and efficacy for the combination of durvalumab and daratumumab in patients with relapsed and refractory multiple myeloma
MEDI4736-MM-005: A Phase II, multicenter, single-arm study to determine the efficacy for the combination of durvalumab plus daratumumab in patients with relapsed and refractory multiple myeloma that have progressed while on current treatment regimen containing daratumumab
MEDI4736-NHL-001: A Phase I/II, open-label, multi-center study to assess the safety and tolerability of durvalumab as monotherapy and in combination therapy in subjects with lymphoma or chronic lymphocytic leukaemia. The only arm in this trial for which enrolment is suspended is the arm with the durval REVLIMID® and rituximab combination
MEDI4736-DLBCL-001: A Phase II, open-label, multicenter study to evaluate the safety and clinical activity of durvalumab in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone (R-CHOP) or with lenalidomide plus R-CHOP (R2 CHOP) in patients with previously untreated, high risk diffuse large B Cell lymphoma

The trial placed on full clinical hold is:

MEDI4736-MM-002: A Phase Ib multicenter, open-label study to determine the recommended dose and regimen of durvalumab in combination with lenalidomide with and without low-dose dexamethasone in subjects with newly diagnosed multiple myeloma

The trials that will continue to enrol are:

MEDI4736-MDS-001: A randomised, multicenter, open-label, Phase II trial evaluating the efficacy and safety of azacitidine subcutaneous in combination with durvalumab in previously untreated subjects with higher-risk myelodysplastic syndromes or in elderly (>= 65 Years) acute myeloid leukaemia subjects not eligible for haematopoietic stem cell transplantation
CC-486-MDS-006: A Phase II, international, multicenter, randomised, open-label, parallel group to evaluate the efficacy and safety of CC-486 alone in combination with durvalumab in subjects with myelodysplastic syndromes who fail to achieve an objective response to treatment with azacitidine for injection or decitabine

In April 2015, Celgene entered into a strategic collaboration with MedImmune to develop and commercialise durvalumab for haematologic malignancies. The use of durvalumab in combination with other agents for the treatment of patients with haematologic malignancies is not approved by the FDA, and the safety and efficacy of those combinations have not been established.

About Celgene
Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. For more information, please visit www.celgene.com.

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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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: 7th September 2017
By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary