ASTRAZENECA PLC
Form 6-K
September 14, 2018

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 2018

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 __

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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): _____

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Yes __ No X

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.
FDA approves AZ's Lumoxiti in hairy cell leukaemia

14 September 2018 07:00 BST

US FDA approves Lumoxiti (moxetumomab pasudotox-tdfk)
for certain patients with relapsed or refractory hairy cell leukaemia

Approval of Lumoxiti, a first-in-class medicine for hairy cell leukaemia
marks first new treatment option for patients in over 20 years1

75% of patients receiving Lumoxiti achieved an
overall response; 30% had a durable complete response2

AstraZeneca and MedImmune, its global biologics research and development arm, announced today that the US Food and Drug Administration (FDA) has approved Lumoxiti (moxetumomab pasudotox-tdfk) for the treatment of adult patients with relapsed or refractory hairy cell leukaemia (HCL) who have received at least two prior systemic therapies, including treatment with a purine nucleoside analog. Lumoxiti is not recommended in patients with severe renal impairment (CrCl ≤ 29 mL/min).2 The Phase III trial results demonstrated 75% (95% confidence interval [CI]: 64, 84) of patients receiving Lumoxiti achieved an overall response; 30% (95% CI: 20, 41) had a durable complete response.2,3

Dave Fredrickson, Executive Vice-President, Global Head Oncology Business Unit, said: "Today's FDA approval of Lumoxiti represents a significant milestone for people living with hairy cell leukaemia, a rare blood cancer that can result in serious and life-threatening conditions. For patients, this approval provides the first FDA-approved medicine for this condition in more than 20 years."

Robert J. Kreitman, MD, Senior Investigator, Head of Clinical Immunotherapy Section, Laboratory of Molecular Biology, Center for Cancer Research, National Cancer Institute, and Principal Investigator of the Phase III clinical trial, said: "While many patients with hairy cell leukaemia experience a remission with current treatments, 30% to 40% will relapse five to ten years after their first treatment.4 With subsequent treatments, durations of response diminish and toxicities accumulate, and few approved treatment options exist.5,6 Moxetumomab pasudotox represents a promising non-chemotherapeutic agent for HCL, addressing an unmet medical need for physicians and their patients."

Lumoxiti was approved under FDA Priority Review.7 The approval is based on data from the Phase III single-arm, open-label '1053' trial of Lumoxiti monotherapy in 80 patients who have received at least two prior therapies, including a purine nucleoside analog.3 The primary endpoint of the trial was durable complete response.3 Summary of key results from the trial, as determined by a blinded independent central review:2

Efficacy measure	Result %, (95% CI)
Durable complete response ratea,b	30% (20, 41)
Overall response ratec	75% (64, 84)
Complete response rated	41% (30, 53)
Partial response ratee	34% (24, 45)
Haematologic remission rateb	80%

a Durable complete response is defined as patients who achieved complete response with haematologic remission for a duration of more than 180 days
b Haematologic remission is defined as haemoglobin > 11g/dL, neutrophils > 1500/mm3, platelets > 100,000/mm3 without transfusions or growth factor for at least 4 weeks
c Overall response rate is defined as best overall response of complete response or partial response
d Complete response is defined as clearing of the bone marrow of hairy cells by routine haematoxylin and eosin stain, radiologic resolution of pre-existing lymphadenopathy and/or organomegaly, and haematologic remission
e Partial response is defined as ≥ 50% decrease or normalisation (< 500/mm3) in peripheral blood lymphocyte count, reduction of pre-existing lymphadenopathy and/or organomegaly, and haematologic remission

The median time to haematologic remission was 1.1 months (range: 0.2 to 13).2 At data cut-off, the median duration of complete response was not yet reached after a median 16.7 months of follow-up.2

Capillary leak syndrome (CLS) and haemolytic uraemic syndrome (HUS), including life-threatening cases of each, have been reported among patients treated with Lumoxiti. In the combined safety database of 129 HCL patients treated with Lumoxiti, Grade 3 or 4 CLS occurred in 1.6% and 2% of patients, respectively. Grade 3 or 4 HUS occurred in 3% and 0.8% of patients, respectively.2

In the '1053' trial of 80 patients, the most common Grade 3 or 4 adverse reactions (reported in at least ≥ 5% of patients) were hypertension, febrile neutropenia, and HUS. HUS was the most common adverse reaction leading to discontinuation (5%). The most common adverse reactions (≥ 20%) of any grade were infusion related reactions (50%), oedema (39%), nausea (35%), fatigue (34%), headache (33%), pyrexia (31%), constipation (23%), anaemia (21%), and diarrhoea (21%). The most common laboratory abnormalities (≥ 20%) of any grade were creatinine increased, ALT increased, hypoalbuminaemia, AST increased, hypocalcaemia, hypophosphataemia, haemoglobin decreased, neutrophil count decreased, hyponatreamia, blood bilirubin increased, hypokalaemia, GGT increased, hypomagnesaemia, platelet count decreased, hyperuricaemia, and alkaline phosphate increased.2

The recommended dose of Lumoxiti is 0.04 mg/kg administered as an intravenous infusion over 30 minutes on days 1, 3, and 5 of each 28-day cycle up to 6 cycles, disease progression, or unacceptable toxicity.2

About hairy cell leukaemia
Hairy cell leukaemia (HCL) is a rare, chronic, and slow-growing leukaemia in which the bone marrow overproduces abnormal B cell lymphocytes.8,9 HCL can result in serious and life-threatening conditions, including infections, bleeding and anaemia.10 Approximately 1,000 people are diagnosed with HCL in the US each year.11 While many patients initially respond to treatment, 30% to 40% will relapse five to ten years after their first treatment.4 With no established standard of care and very few treatments available, there remains significant unmet medical need for people with relapsed or refractory HCL.4,8

About Lumoxiti
Lumoxiti (moxetumomab pasudotox, formerly CAT8015 or HA22) is a CD22-directed cytotoxin and a first-in-class treatment in the US for adult patients with relapsed or refractory hairy cell leukaemia (HCL) who have received at least two prior systemic therapies, including treatment with a purine nucleoside analog. Lumoxiti is not recommended in patients with severe renal impairment (CrCl ≤ 29 mL/min).2 It comprises the CD22 binding portion of an antibody fused to a truncated bacterial toxin; the toxin inhibits protein synthesis and ultimately triggers apoptotic cell death.2 Lumoxiti has been granted Orphan Drug Designation by the FDA for the treatment of HCL.

About the '1053' Phase III trial
The '1053' trial is a single-arm, multicentre Phase III clinical trial assessing the efficacy, safety, immunogenicity and pharmacokinetics of moxetumomab pasudotox monotherapy in patients with relapsed or refractory HCL who have received at least two prior therapies, including one purine nucleoside analog. The trial was conducted in 80 patients

across 34 sites in 14 countries. The primary endpoint was durable complete response (CR), defined as CR with haematologic remission (blood count normalisation) for >180 days. Secondary outcome measures included overall response rate, relapse free survival, progression-free survival, time to response, safety, pharmacokinetic and immunogenic potential.7

Early discovery of moxetumomab pasudotox was led by the National Cancer Institute (NCI). The collaboration between NCI and MedImmune, AstraZeneca's global biologics research and development arm, is an example of how scientific partnerships can lead to important advances for cancer patients.

About AstraZeneca in Haematology
Leveraging its strength in oncology, AstraZeneca has established haematology as one of four key oncology disease areas of focus and is accelerating development of a broad portfolio of potential blood cancer treatments. AstraZeneca and Acerta Pharma, its haematology research and development centre of excellence, received US FDA approval for the first medicine in this franchise, Calquence (acalabrutinib), in October 2017.

About AstraZeneca in Oncology
AstraZeneca has a deep-rooted heritage in Oncology and offers a quickly-growing portfolio of new medicines that has the potential to transform patients' lives and the Company's future. With at least six new medicines to be launched between 2014 and 2020, and a broad pipeline of small molecules and biologics in development, we are committed to advance Oncology as a growth driver for AstraZeneca focused on lung, ovarian, breast and blood cancers. In addition to our core capabilities, we actively pursue innovative partnerships and investments that accelerate the delivery of our strategy, as illustrated by our investment in Acerta Pharma in haematology.

By harnessing the power of four scientific platforms - Immuno-Oncology, Tumour Drivers and Resistance, DNA Damage Response and Antibody Drug Conjugates - and by championing the development of personalised combinations, AstraZeneca has the vision to redefine cancer treatment and one day eliminate cancer as a cause of death.

About MedImmune
MedImmune is the global biologics research and development arm of AstraZeneca, a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of small molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across Oncology, Respiratory, Cardiovascular, Renal & Metabolic Diseases, and Infection and Vaccines. The MedImmune headquarters is located in Gaithersburg, MD, one of AstraZeneca's three global R&D centres, with additional sites in Cambridge, UK and South San Francisco, CA. For more information, please visit www.medimmune.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 therapy areas - Oncology, Cardiovascular, Renal & Metabolism and Respiratory. 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
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AstraZeneca PLC

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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: 14 September 2018

By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary