

ASTRAZENECA PLC  
Form 6-K  
September 29, 2014

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 2014

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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

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ASTRAZENECA UPDATES ON PROGRESS OF ONCOLOGY PIPELINE AT ESMO 2014 CONGRESS

AstraZeneca has presented new data from its pipeline of investigational cancer medicines at the European Society of Medical Oncology (ESMO) 2014 Congress in Madrid. Together with MedImmune, its global biologics research and development arm, the company presented data from over 40 abstracts, building on results highlighted earlier this year at the American Society for Clinical Oncology (ASCO) congress.

Highlights include:

- . Preliminary results in the ongoing Phase I MEDI4736 (PD-L1) + tremelimumab (CTLA-4) combination study in patients with non-small cell lung cancer (NSCLC) who have already received prior cancer treatments.
- . Updated data from a Phase I monotherapy study of MEDI4736 in patients with metastatic squamous cell carcinoma of the head and neck (SCCHN).
- . Further data from the Phase I/II study of AZD9291 in patients with epidermal growth factor receptor mutation positive (EGFRm) T790M+ advanced NSCLC who had disease progression following treatment with an EGFR tyrosine kinase inhibitor (TKI).

Briggs Morrison, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca said: "At ASCO we presented data demonstrating the strength and rapid progression of our oncology pipeline, which we believe has the potential to redefine the way cancer patients are treated. The data presented here at the ESMO 2014 Congress further builds our clinical understanding of the key assets across our core areas of focus: immuno-oncology, the genetic drivers of cancer and acquired resistance and DNA damage repair. We are encouraged by the results we are seeing and look forward to providing further updates as we continue to work at pace to get these potentially life-changing medicines to patients."

Immuno-oncology

MedImmune presented updates on its novel immunotherapy portfolio at the ESMO 2014 Congress through eight abstracts, which reinforce the clinical activity and tolerability of MEDI4736 as monotherapy and highlight the potential of the combination of MEDI4736 and tremelimumab.

Specifically, preliminary data was presented on Saturday, 27 September from the ongoing Phase I study of MEDI4736 in combination with tremelimumab in NSCLC patients who have already received prior cancer treatments (Antonia, abstract #1327P). The data covered anti-tumour activity and the tolerability profile of the combination.

"We are pleased with the results from MEDI4736 in combination with tremelimumab," said Edward Bradley, Senior Vice President, R&D and Oncology iMED Head, MedImmune. "While it is still early with a limited data set, the tolerability profile is encouraging. We have also seen some evidence of clinical activity in patients who have failed prior lines of therapy and whose tumour does not express PD-L1. This supports our strategy to explore this combination more broadly, particularly in the PD-L1 negative population. This trial will identify the optimal dose to take into our Phase III clinical programme."

MEDI4736 is an investigational, engineered, human monoclonal antibody directed against an immune system 'checkpoint', known as programmed cell death ligand 1 (PD-L1).

Tremelimumab targets a separate immune checkpoint, CTLA-4. Several

checkpoints such as PD-L1 and CTLA-4, which the body normally uses to dampen the immune response, can be hijacked by tumour cells to escape detection by the immune system and facilitate malignant growth.

Immunotherapies are designed to enable the immune system to counteract these tactics employed by cancer cells. By targeting more than one hijacked checkpoint, combination therapies have the potential to be more effective than monotherapy in treating this disease.

MedImmune has initiated additional Phase I immunotherapy combination trials, including MEDI4736 + MEDI0680 (PD-1) and MEDI4736 + MEDI6469 (OX40)\*.

Ongoing Phase I data were also presented on Saturday, 27 September, assessing the clinical activity and safety profile of MEDI4736 as a monotherapy in patients with NSCLC (Antonia, abstract #1325P). On Sunday, 28 September, MedImmune presented additional MEDI4736 monotherapy data in a Phase I dose-expansion study of patients with solid tumours. This data set provided further information on the clinical activity and tolerability profile of MEDI4736 across a range of solid tumours, including pancreatic cancer, gastric cancer and hepatocellular cancer (Segal, abstract #1058PD).

A separate analysis of patients with metastatic SCCHN was also shared (Fury, abstract #988PD).

The Phase I data, coupled with the pre-clinical data, support the accelerated development of MEDI4736 into Phase III clinical trials in both NSCLC and SCCHN.

Separately, MedImmune has also recently commenced a Phase I human OX40 agonist (MEDI6383) monotherapy study in cancer patients with recurrent or metastatic solid tumors.

#### Small molecules

On Sunday, 28 September, AstraZeneca presented updates on key assets in its small molecule portfolio, including the investigational NSCLC medicine AZD9291, a highly selective, irreversible inhibitor of both the activating sensitising EGFR mutation (EGFRm) and the resistance mutation T790M, IRESSA® (gefitinib) and the PARP inhibitor olaparib.

Updated data from the ongoing AURA Phase I/II study (Yang, Abstract #449PD) provided an update on the activity and safety of AZD9291 in patients with EGFRm T790M+ advanced NSCLC whose disease had progressed following treatment with an EGFR TKI. This builds on data from the AURA study presented earlier in the year at ASCO.

AstraZeneca has initiated both Phase II and Phase III studies in this patient population (AURA 2 and AURA 3 respectively).

In addition, a Phase III study evaluating AZD9291 in first line EGFRm advanced NSCLC is scheduled to start later this year.

AstraZeneca is also currently investigating combinations of AZD9291 with MEDI4736, and with other investigational drugs selumetinib (small molecule MEK inhibitor) and AZD6094 (small molecule MET inhibitor) in NSCLC.

Antoine Yver, Head of Oncology, Global Medicines Development, AstraZeneca, said "The updated data we have presented at the ESMO 2014 Congress reinforce our strategy of moving rapidly into Phase III development with AZD9291 in EGFRm T790M+ advanced non-small cell lung cancer. We have already made significant progress with our accelerated development programme and we anticipate filing for regulatory approval in the US in the second half of 2015."

AstraZeneca also presented data from the Phase III IMPRESS study for IRESSA, a second line, combination study in patients with EGFRm advanced NSCLC who have acquired resistance to first line IRESSA.

Separately, new data was presented on the impact of olaparib on the quality of life of patients with BRCA mutated platinum-sensitive relapsed ovarian cancer. The Committee for Medicinal Products for Human Use is expected to provide its opinion on olaparib in the EU on 23 October 2014, and the US FDA Prescription Drug User Fee Act date is set for 3 January 2015.

AstraZeneca hosted a briefing for analysts and investors at the ESMO 2014 Congress on the evening of Sunday, 28 September 2014. The presentation from the event is available at: [astrazeneca.com/investors](http://astrazeneca.com/investors).

\*MEDI6469 is an in-licensed asset from Agonox.

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 commercialization of small molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across key therapeutic areas, including respiratory, inflammation and autoimmunity; cardiovascular and metabolic disease; oncology; neuroscience; and infection and vaccines. The MedImmune headquarters is located in Gaithersburg, Md., one of AstraZeneca's three global R&D centers. For more information, please visit [www.medimmune.com](http://www.medimmune.com).

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. 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](http://www.astrazeneca.com)

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29 September 2014

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SIGNATURES

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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: 29 September 2014

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