

ASTRAZENECA PLC
Form 6-K
May 15, 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 May 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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Yes No

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ASTRAZENECA TO DEMONSTRATE THE STRENGTH AND RAPID ACCELERATION OF ITS ONCOLOGY
PIPELINE AT ASCO 2014

Preliminary data* released ahead of full data presentations at ASCO, 30 May-3 June

New data from AstraZeneca's investigational cancer medicines demonstrate the rapid progression of its oncology pipeline. Over 40 scientific abstracts from AstraZeneca and its global biologics R&D arm MedImmune will be featured at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO) at the end of this month.

Data will be reported for a number of innovative molecules in different tumour types. Highlights include:

- In the MEDI4736 Phase I trial to date we have seen durable clinical activity and acceptable safety for this investigational anti-PD-L1 antibody.
- Data from the large Phase I study of AZD9291 has shown that it was well tolerated and clinically active in patients with EGFR mutation positive (EGFRm+) non-small cell lung cancer (NSCLC) who have developed acquired resistance to EGFR tyrosine-kinase inhibitors (TKIs).
- Encouraging efficacy data shown in a randomised Phase II study, conducted by the US National Cancer Institute (NCI), investigating the combination of PARP inhibitor olaparib and VEGF inhibitor cediranib in high-grade serous ovarian cancer.

Briggs Morrison, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca said: "We believe that our rich oncology pipeline has the potential to redefine the way that cancer patients are treated. We continue to deliver on our late stage assets and drive our scientific leadership in oncology, as clearly demonstrated by the recent accelerated development of key assets.

"The preliminary data made available today highlight our strength across our three core areas of oncology research: immuno-oncology, our focus on the genetic drivers of cancer and acquired resistance and DNA damage repair. We are looking forward to the presentation of the full data sets at ASCO."

Harnessing the potential of immuno-oncology

MedImmune is building a comprehensive immuno-oncology programme, with MEDI4736 as one of the leading late stage assets. Data from the ongoing MEDI4736 Phase I study to be presented at ASCO has to date shown encouraging clinical activity and acceptable safety across a range of tumour types.

The results of this Phase I study, coupled with the pre-clinical data and validation of this target supported the accelerated development of MEDI4736 into Phase III clinical trials. The late stage clinical programme for MEDI4736 will evaluate the compound in NSCLC at different stages of disease. Patients were recently randomised into the Phase III PACIFIC study, which is investigating patients with locally advanced unresectable NSCLC (Stage III) following chemoradiation. A second Phase III study, ARCTIC, will investigate MEDI4736 as monotherapy in patients with advanced or metastatic NSCLC who have failed on two or more prior therapies, and planned in combination with tremelimumab.

Data from an ongoing study exploring MEDI4736 in combination with tremelimumab in lung cancer will be presented as part of a briefing for analysts and investors in Chicago on 2 June 2014.

MedImmune is also exploring tremelimumab (anti-CTLA 4) in a pivotal study for malignant mesothelioma, a patient population with a very high unmet need. Updated Phase II data from an investigator initiated trial exploring tremelimumab in malignant mesothelioma will be available at ASCO.

"Immuno-oncology is developing at a rapid pace and redefining the cancer treatment landscape. We are committed to realising the full potential of this promising therapeutic approach," said Bahija Jallal, Executive Vice President,

MedImmune. "We believe that combinations of immunotherapies, both with each other and with highly targeted small molecules, will be the key to achieving the greatest patient benefit. With the AstraZeneca and MedImmune combined portfolio, we are uniquely positioned to explore this possibility and have already initiated multiple combination studies with MEDI4736."

Two oral presentations and a poster highlights session will showcase data from the Phase I study (abstract #3001 in patients with solid tumours, abstract #3002, a multi-arm expansion study and abstract #8021, a clinical activity and biomarker analysis of MEDI4736 in patients with treatment-naïve or pre-treated NSCLC).

Targeted treatments in lung cancer

Despite the efficacy of currently approved TKIs, for patients who have the EGFR mutation positive form of NSCLC, resistance to treatment is a significant barrier to long term disease control. In approximately half of these patients this resistance is caused by the secondary mutation known as T790M and there are currently no therapies specifically approved for them. AZD9291 is a highly selective, irreversible inhibitor of both the activating sensitising EGFR mutation (EGFRm+) and the activating resistance mutation, T790M, while sparing the activity of wild type EGFR.

Updated data from the ongoing Phase I AURA study show that to date AZD9291 is well tolerated and has demonstrated sustainable anti-cancer activity in lung cancer patients whose tumours are EGFR mutation positive and have become resistant to EGFR TKIs. Specifically, the data from this trial demonstrate that patients with EGFR T790M+ tumours have a higher overall response rate than patients whose tumours have not acquired this resistance mutation. The data will be presented as an oral abstract (abstract #8009) and was selected from over 5,000 study abstracts for inclusion in the official ASCO programme.

AZD9291 was recently granted Breakthrough Therapy Designation by the US FDA for patients with metastatic EGFR T790M mutation-positive NSCLC, whose disease has progressed following treatment with an EGFR TKI. The Breakthrough designation allows AstraZeneca to expedite the US development of AZD9291. AstraZeneca plans to begin Phase III trials soon.

Driving the potential of combinations

Combination therapies have the potential to be one of the most effective ways of treating cancer. Results from the NCI led Phase II study investigating the combination of olaparib, a potential first-in-class oral poly ADP-ribose polymerase (PARP) inhibitor, and cediranib, a potent inhibitor of vascular endothelial growth factor (VEGF) receptor tyrosine kinases, in women with ovarian cancer will be presented as a Late Breaking Abstract (abstract LBA5500).

Olaparib has already shown efficacy as a monotherapy and was recently granted Priority Review by the FDA for the treatment of platinum sensitive relapsed ovarian cancer patients who have a BRCA mutation. Additionally, in the Phase III (ICON 6) trial, cediranib demonstrated significant improvements in progression free survival and overall survival in platinum sensitive relapsed ovarian cancer, when given during and after chemotherapy, compared to chemotherapy alone.

During the ASCO conference AstraZeneca will host a briefing for analysts and investors, to be held in Chicago on 2 June 2014.

KEY ASTRAZENECA ABSTRACTS TO BE FEATURED AT ASCO

* Data included in abstracts is preliminary only and does not necessarily represent full data sets.

Oral presentations, included in official programme:

- #3001 Lutzky J, et al. A Phase 1 study of MEDI4736, an Anti-PD-L1 Antibody, in Patients With Advanced Solid Tumors. Oral presentation, 09.57am - 10.09am 3 June 2014.
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#3002 Segal NH, et al. Preliminary Data from a Multi-Arm Expansion Study of MEDI4736, an Anti-PD-L1 Antibody. Oral presentation, 10.09am - 10.21am 3 June 2014.

- #8009 Janne P, et al. Clinical activity of the mutant selective EGFR Inhibitor AZD9291 in patients (pts) with EGFR inhibitor resistant non-small cell lung cancer (NSCLC). Oral presentation 8.00am - 8.12am 31 May 2014.

Late breaking abstract:

- #LBA5500 Liu JF, et al. A randomized phase 2 trial comparing efficacy of the combination of the PARP inhibitor olaparib and the anti-angiogenic cediranib against olaparib alone in recurrent platinum-sensitive ovarian cancer. Oral presentation 1:15 PM - 1:27 PM 31 May 2014.

Other key MEDI4736 abstracts to be featured:

- #TPS3120[^] Callahan MK, et al. A phase 1 study to evaluate the safety and tolerability of MEDI4736, an anti-PD-L1 antibody, in combination with tremelimumab in patients with advanced solid tumours. General poster session 8:00 AM - 11:45 AM 1 June 2014.
- #TPS9108 Gordon MS, et al. Phase 1 study of MEDI4736, an anti-PD-L1 antibody, in combination with dabrafenib and trametinib or trametinib alone in patients with unresectable or metastatic melanoma. General poster session 8:00 AM - 11:45 AM 31 May 2014.
- #3012 Hyman D, et al. A phase 1 study of MEDI3617, a selective angiopoietin-2 inhibitor, alone and in combination with carboplatin/paclitaxel, paclitaxel, or bevacizumab in patients with advanced solid tumors. General poster session 1:15 PM - 4:15 PM 2 June 2014.
- #8021 Brahmer J, et al. Clinical activity and biomarkers of MEDI4736, an anti-PD-L1 antibody, in patients with NSCLC. Poster highlights session 8:00 AM - 11:00 AM 3 June 2014.
- #2602 Fairman D, et al. Pharmacokinetics of MEDI4736, a fully human anti-PDL1 monoclonal antibody, in patients with advanced solid tumours. General poster session 8:00 AM - 11:45 AM 1 June 2014.

Other key AZD9291 abstract to be featured:

- #8092 Thress K, et al. EGFR mutation detection in ctDNA isolated from NSCLC patient plasma; a cross-platform comparison of leading technologies to support the clinical development of AZD9291. General poster session 1:15 PM - 5:00 PM 31 May 2014.

Other key olaparib abstracts to be featured:

- #TPS5616 Moore K, et al. SOLO1 and SOLO2: Randomized phase III trials of olaparib in patients (pts) with ovarian cancer and a BRCA1/2 mutation (BRCAm). General poster session 8:00 AM - 11:45 AM 31 May 2014.
- #2599 Vergote I, et al. Effect of food on the pharmacokinetics (PK) of olaparib after oral dosing of the capsule formulation. General poster session 8:00 AM - 11:45 AM 1 June 2014.
- #5534 Lheureux S, et al. Characterization of ovarian cancer long-term responders on olaparib. General poster session 8:00 AM - 11:00 AM 2 June 2014.
- #5536 Dougherty B, et al. Analysis of candidate homologous repair deficiency genes in a clinical trial of olaparib in patients (pts) with platinum-sensitive, relapsed serous ovarian cancer (PSR SOC). Poster Highlights session 8:00 AM - 11:00 AM 2 June 2014.

Other abstracts to be featured:

- #11111 Gan H, et al. First-in-human phase I study of a selective c-Met inhibitor volitinib (HMP504/AZD6094) in patients with advanced solid tumors General Poster Session 1:15 PM - 5:00 PM 31 May 2014.
- #2510 Matulonis U, et al. Phase I study of oral BKM120 and oral olaparib for high-grade serous ovarian cancer (HGSC) or triple-negative breast cancer (TNBC). Oral presentation 8:12 AM - 8:24 AM 31 May 2014 (ISS)
- #2607 Banerji U, et al. TAX-TORC: A phase I trial of the combination of AZD2014 (dual mTORC1/mTORC2 inhibitor) and weekly paclitaxel in patients with solid tumours. General poster session 8:00 AM - 11:45 AM 1 June 2014

About MEDI4736

MEDI4736 is an investigational, engineered, human monoclonal antibody directed against programmed cell death ligand 1 (PD-L1). Signals from PD-L1 help tumours avoid detection by the immune system. It is believed that by targeting PD-L1, MEDI4736 may block this ligand from sending out a signal to T cells to 'ignore' tumour cells, thereby countering cancer's immune-evading tactics. MEDI4736 is being developed alongside other immunotherapies (IMTs) - which AstraZeneca/MedImmune believe have the potential to shape the future of cancer treatment - particularly if used in combination with other highly-active molecules.

About tremelimumab

Tremelimumab is an investigational, fully human monoclonal IgG2 antibody which binds to the protein CTLA-4, expressed on the surface of activated T cells. It is one of the only molecules in development for treating mesothelioma by blocking CTLA-4 to strengthen immune system response.

About AZD9291

AZD9291 is a highly selective, irreversible inhibitor of both the activating sensitising EGFR mutation (EGFR^{m+}) and the activating resistance mutation, T790M, while sparing the activity of wild type EGFR. Patients with EGFR^{m+} NSCLC are particularly sensitive to treatment with currently available EGFR TKIs, which block the cell signalling pathways that drive the growth of tumour cells. However, tumour cells almost always develop resistance to treatment, leading to disease progression. In approximately half of patients, this resistance is caused by the secondary mutation known as T790M. There are currently no targeted therapies approved for the treatment of tumours with this resistance mutation.

In the ongoing Phase I study, AZD9291 has shown early evidence of activity as a once-daily monotherapy with clinical responses observed in an EGFR^{m+} population of patients with NSCLC who have previously failed on EGFR TKIs and also in patients with the T790M mutation. To date, AZD9291 has been well-tolerated with low rates of side effects.

About olaparib

Olaparib is a potential first-in-class oral poly ADP-ribose polymerase (PARP) inhibitor that has been shown to exploit DNA repair pathway deficiencies to preferentially kill cancer cells. This mode of action gives olaparib the potential for development in a range of tumour types with DNA repair deficiencies. PARP is a key enzyme in one of the DNA repair pathways in human cells. Inhibition of PARP results in a build-up of DNA damage in the cell, requiring repair via an alternative pathway called Homologous Recombination repair (HR). Cancer cells that already have a deficient HR pathway (HRD) are limited in their ability to repair their DNA, overloading them with DNA damage and causing them to die. A number of abnormalities can cause HRD in cancer cells including BRCA gene mutations. PARP is associated with a range of tumour types, in particular with breast and ovarian cancers.

The US Food and Drug Administration (FDA) has granted Priority Review for olaparib, in the treatment of ovarian cancer patients who have a BRCA mutation and whose cancer has relapsed following a complete or partial response to platinum-based chemotherapy.

About cediranib

Cediranib is a potent selective oral inhibitor of cell signalling through Vascular Epidermal Growth Factor (VEGF) receptors, resulting in tumour cell death by restricting blood supply to the tumour site.

Angiogenesis, the formation of new blood vessels, is essential for normal biologic processes such as wound healing and the renewal of the uterine lining. However, angiogenesis can also facilitate cancer growth and metastasis by supporting the development of new blood vessels that then supply the tumour with nutrients and oxygen. Angiogenesis therefore constitutes an important point in the control of cancer progression and its inhibition has become a valuable approach to treatment for multiple cancers. Angiogenesis is highly dependent on the vascular endothelial growth factor (VEGF) signalling pathway. VEGF and VEGF receptors (VEGFRs) are often over expressed in cancer and are associated with a poor prognosis. Inhibiting VEGF signalling interferes with this process,

effectively "starving" the tumour of the oxygen and nutrients it needs to grow.

Cediranib is currently being evaluated in an ongoing clinical development programme, including studies in multiple tumours.

About MedImmune

MedImmune is the worldwide biologics research and development arm of AstraZeneca. 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 centres. For more information, please visit 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

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14 May 2014

-ENDS-

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: 15 May 2014

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