The following amendment(s) has (have) been made to the 'Tagrisso significantly improves overall survival in the Phase III FLAURA trial for 1st-line EGFR-mutated non-small cell lung cancer' announcement released on 09 August 2019 at 07:00 BST.

Correction: Tagrisso 40mg and 80mg once-daily oral tablets are not approved in China for 1st-line EGFRm advanced NSCLC. Tagrisso has received approval in more than 70 countries, including the US, Japan and the EU, for 1st-line EGFRm advanced NSCLC, and in more than 80 countries, including the US, Japan, China and the EU, for 2nd-line use in patients with EGFR T790M mutation-positive advanced NSCLC.

All other details remain unchanged.

The full amended text is shown below.

9 August 2019 07:00 BST

Tagrisso significantly improves overall survival in the Phase III FLAURA trial for 1st-line EGFR-mutated non-small cell lung cancer

Tagrisso is the only medicine demonstrating statistically-significant overall survival benefit in this setting. Also increased the time patients with central nervous system metastases lived without disease progression

AstraZeneca today announced positive overall survival (OS) results from the Phase III FLAURA trial, a randomised, double-blinded, multi-centre trial of *Tagrisso* (osimertinib) in previously-untreated patients with locally-advanced or metastatic non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) mutations.

Tagrisso showed a statistically-significant and clinically-meaningful improvement in OS, a secondary endpoint in the FLAURA Phase III trial, compared with erlotinib or gefitinib both of which were previous standard-of-care (SoC) treatments in this setting. The FLAURA trial met its primary endpoint in July 2017, showing a statistically-significant and clinically-meaningful improvement in progression-free survival (PFS), increasing the time patients lived without disease progression or death from any cause. The safety and tolerability of *Tagrisso* was consistent with its established profile.

José Baselga, Executive Vice President, Oncology R&D said: "Today's positive results show that *Tagrisso* provides an unprecedented survival outcome versus previous standard-of-care epidermal growth factor receptor tyrosine kinase inhibitors, reaffirming *Tagrisso* as the 1st-line standard-of-care for EGFR-mutated metastatic non-small cell lung cancer."

AstraZeneca plans to present the OS results from the FLAURA trial at a forthcoming medical meeting.

Tagrisso is currently approved in 74 countries, including the US, Japan and the EU, for 1st-line EGFRm metastatic NSCLC.

About lung cancer

Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-fifth of all cancer deaths, more than breast, prostate and colorectal cancers combined.[1]Lung cancer is broadly split into NSCLC and small cell lung cancer (SCLC), with 80-85% classified as NSCLC.[2] Approximately 10-15% of NSCLC patients in the US and Europe, and 30-40% of patients in Asia have EGFR-mutated (EGFRm) NSCLC.[3-5] These

patients are particularly sensitive to treatment with EGFR-tyrosine kinase inhibitors (TKI) which block the cell-signalling pathways that drive the growth of tumour cells. Approximately 25% of patients with EGFRm NSCLC have brain metastases at diagnosis, increasing to approximately 40% within two years of diagnosis.[6] The presence of brain metastases often reduces median survival to less than eight months.[7]

About *Tagrisso*
Tagrisso (osimertinib) is a third-generation, irreversible EGFR-TKI designed to inhibit both EGFR-sensitising and EGFR T790M-resistance mutations, with clinical activity against central nervous system metastases. *Tagrisso* 40mg and 80mg once-daily oral tablets have now received approval in more than 70 countries, including the US, Japan and the EU, for 1st-line EGFRm advanced NSCLC, and in more than 80 countries, including the US, Japan, China and the EU, for 2nd-line use in patients with EGFR T790M mutation-positive advanced NSCLC. *Tagrisso* is also being developed in the adjuvant setting (ADAURA trial), in the locally-advanced unresectable setting (LAURA), in combination with chemotherapy (FLAURA2) and with potential new medicines (SAVANNAH, ORCHARD).

About FLAURA
The FLAURA trial assessed the efficacy and safety of *Tagrisso* 80mg orally once daily vs. comparator EGFR-TKIs (either erlotinib [150mg orally, once daily] or gefitinib [250mg orally, once daily]) in previously-untreated patients with locally-advanced or metastatic EGFRm NSCLC. The trial was double-blinded and randomised, with 556 patients across 29 countries.

About AstraZeneca in lung cancer
AstraZeneca has a comprehensive portfolio of approved and potential new medicines in late-stage clinical development for the treatment of different forms of lung cancer spanning several stages of disease, lines of therapy and modes of action. We aim to address the unmet needs of patients with EGFR-mutated tumours as a genetic driver of disease, which occur in 10-15% of NSCLC patients in the US and EU and 30-40% of NSCLC patients in Asia, with our approved medicines *Iressa*(gefitinib) and *Tagrisso,* and ongoing Phase III trials ADAURA, LAURA, FLAURA and FLAURA2 as well as the Phase II combination trials SAVANNAH and ORCHARD.[3-5]

Our extensive late-stage Immuno-Oncology programme focuses on lung cancer patients without a known genetic mutation which represents up to 50% of all patients with lung cancer. *Imfinzi*(durvalumab), an anti-PDL1 antibody, is in development as monotherapy (Phase III trials ADJUVANT BR.31, PACIFIC-4, PACIFIC-5, and PEARL) and in combination with tremelimumab and/or chemotherapy (Phase III trials AEGEAN, PACIFIC-2, NEPTUNE, POSEIDON, ADRIATIC and CASPIAN).

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 key 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 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, CVRM and Respiratory. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit astrazeneca.com and follow us on Twitter @AstraZeneca.

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