

9th August 2018

The Manager- Listing
BSE Limited
Corporate Relationship Dept., 5th Floor, New Trading Ring
Rotunda Building, P J Towers, Dalal Street, Fort,
Mumbai - 400001

The Manager- Listing
National Stock Exchange of India Limited
Exchange plaza, 5th Floor, Plot No. C/1, G Block
Bandra –Kurla Complex, Bandra (E),
Mumbai - 400051

Dear Sir(s),

Sub: AstraZeneca Pharma India Limited receives Import and Market Permission in Form 45 (Marketing Authorization – Additional Indication) from Drug Controller General of India (DCGI) for Osimertinib Tablet 40 mg and 80 mg.

This is to inform that AstraZeneca Pharma India Limited has received Import and Market permission in Form 45 (Marketing Authorization- Additional Indication) from the Drugs Controller General of India for Osimertinib Tablet 40 mg and 80 mg (Tagrisso™) indicated as **first-line treatment of patients** with locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) whose tumours have Epidermal Growth Factor Receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitutions mutations.

The receipt of this Import and Market permission paves way for the launch of Osimertinib Tablets (Tagrisso™) for first-line treatment of patients in India, subject to the receipt of other related statutory approvals and licenses.

The first-line use of Osimertinib offers potential new standard of care.

Please find attached a copy of the Press-Release dated 9th August 2018 being issued by the Company in connection with the above.

Kindly take the same on record.

For AstraZeneca Pharma India Limited



Pratap Rudra
Company Secretary & Legal Counsel



Business Press Release

AstraZeneca receives marketing permission for Osimertinib (Tagrisso™) as 1st line treatment for EGFRm advanced Non-Small Cell Lung Cancer (NSCLC) in India

1st line use of Osimertinib offers potential new standard of care

Bengaluru, 9 August 2018: AstraZeneca Pharma India Limited (AZPIL) today announced that it has received Import & Market permission – additional indication for osimertinib (Tagrisso™) Tablet 40 mg and 80 mg, as 1st line treatment for EGFRm advanced Non-Small Cell Lung Cancer (NSCLC) by the Drug Controller General of India (DCGI). The receipt of this permission paves way for the launch of osimertinib in India for 1st line treatment.

Osimertinib is indicated **for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitutions mutations.**

Osimertinib is **already approved and available for the treatment of patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an appropriate test, whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.** AstraZeneca has been pioneering access to T790M mutation testing in India through interventions in infrastructure, scientific knowledge dissemination to medical and pathological experts and standardization of test quality through independent External Quality Assurance (EQA) programs.

In 2017, osimertinib was granted '**Breakthrough Therapy**' status and 'Priority Review' designations by the US FDA in 1st line treatment setting. osimertinib is a patented product of AstraZeneca group.

Mr. Gagan Singh Bedi, Managing Director, AstraZeneca Pharma India Limited said, "Lung cancer is the leading cause of cancer related mortality in India. In spite of therapeutic advances, the overall 5-year survival rate of lung cancer is dismal at <5% in India. Tagrisso's approval in first line treatment is an exciting advance in bringing a potential new standard of care to patients with EGFRm advanced NSCLC in India. Clinical data suggests early and sustained benefit with Osimertinib in first line treatment that has the potential to significantly impact long-term patient outcomes and help address the considerable unmet need that remains in the treatment of lung cancer."

Lung cancer is the leading cause of cancer related mortality world-wide and amongst males in India with 5-years survival rates as dismal as 3.7% in India [1,2]. Various studies have suggested that nearly all the lung cancer cases are non-small cell lung cancers (NSCLC), of which EGFR-TKI sensitising mutations are observed in 23 – 50% of patients [3]. These patients are particularly sensitive to EGFR-TKIs, which block the cell-signaling pathways that drive the growth of tumour cells. However, tumours almost always develop resistance to EGFR-TKI treatment, leading to disease progression.

Nearly 28-54% of EGFRm advanced NSCLC patients, whose disease progresses after treatment with an EGFR TKI, develop resistance due to the T790M resistance mutation [4,5]. There is also a need for medicines with improved CNS efficacy since approximately 16% patients with EGFRm NSCLC have brain metastases at diagnosis, increasing to approximately half of patients within 3 years of diagnosis [6,7].

Osimertinib (Tagrisso) is a third-generation, irreversible EGFR-TKI designed to inhibit both EGFR-sensitising (exon 19 deletions or exon 21 (L858R) substitutions mutations) and EGFR T790M-resistance mutations, with clinical activity against CNS metastases.

NOTE TO EDITORS:

About Osimertinib (Tagrisso™)

Osimertinib is a third-generation, irreversible, oral EGFR-TKI that potently and selectively inhibits both EGFRm and EGFR T790M resistance mutations, spares wild-type EGFR, and has demonstrated clinical activity in CNS metastases. Tagrisso™ 40mg and 80mg once-daily oral tablets have been approved in the US and Brazil for 1st-line EGFRm advanced NSCLC, and in many other countries including the US, EU, Japan and China for patients with EGFR T790M mutation-positive advanced NSCLC.

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 –Cardiovascular Renal & Metabolic Disease, Oncology and Respiratory & Autoimmunity. The Company is also active in inflammation, infection and neuroscience through numerous collaborations. 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

About AstraZeneca Pharma India Limited

AstraZeneca Pharma India Limited was established in 1979 and is headquartered at Bengaluru, Karnataka. AstraZeneca Pharma India Limited has a workforce of over 1200 employees across the country that is committed to deliver great medicines to patients through innovative science and global excellence in development and commercialization. For more information, please visit:

www.astrazeneca.com/india

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Sources:

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