

Date: 21st June 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) from Drug Controller General of India (DCGI) for durvalumab (Imfinzi™)

This is to inform that AstraZeneca Pharma India Limited has received Import and Market permission in Form 45 (Marketing Authorization) from the Drug Controller General of India for *durvalumab* (Imfinzi™).

The receipt of this Import and Market permission paves way for the launch of *durvalumab* (Imfinzi™) in India, subject to the receipt of other related statutory approvals and licenses.

Durvalumab provides a treatment option for patient with locally advanced, unresectable Non-Small Cell Lung Cancer (NSCLC) and metastatic urothelial carcinoma.

Please find attached a copy of the Press-Release dated 21st June 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 Durvalumab (Imfinzi™) in India

- Durvalumab is the only immunotherapy approved for patients with unresectable Stage III Non-Small Cell Lung Cancer (NSCLC)
- Durvalumab was granted US FDA 'breakthrough therapy' designation on July 31, 2017.

Bengaluru, 21 June 2018: AstraZeneca Pharma India Limited (AZPIL) today announced that it has received Import & Market permission for Durvalumab (Imfinzi™) in India by the Drug Controller General of India (DCGI). The receipt of this permission paves way for the launch of durvalumab (Imfinzi™) in India, subject to the receipt of further related statutory approvals and licenses.

Durvalumab provides a treatment option for patient with locally advanced, unresectable Non-Small Cell Lung Cancer (NSCLC) and metastatic urothelial carcinoma.

Durvalumab is a patented product of AstraZeneca global.

Gagan Singh, Managing Director, AstraZeneca Pharma India Limited said, "The import and market permission for Durvalumab for unresectable stage III Non-Small Cell Lung Cancer (NSCLC) and locally advanced or metastatic urothelial carcinoma is a significant milestone for patients who have currently limited treatment options. In India, approximately one third of patients with NSCLC are present with Stage III disease and we are excited to bring the first immunotherapy into this setting for patients."

AstraZeneca's Durvalumab is a part of a new class of immunotherapy drugs known as 'checkpoint inhibitors'. Some forms of bladder and lung cancer use the PD-L1 protein to evade the immune system. Durvalumab, is a human monoclonal antibody that binds to PD-L1 and blocks the interaction of PD-L1 with PD-1 and CD80, countering the tumour's immune-evading tactics and releasing the inhibition of immune responses.

About Stage III NSCLC and Urothelial cancer

NSCLC accounts for about 85% of all lung cancers (1). In general, lung cancer is the most common cancer in Indian men and accounts for most number of deaths (13.7%) from cancer (2). Incidence of Stage III NSCLC in one study in India was found to be 28.7 %, representing approximately one-third of NSCLC incidence (3).

Stage III (locally advanced) NSCLC is commonly divided into three sub-categories (IIIA, IIIB and IIIC), defined by how much the cancer has spread locally and the possibility of surgery. This differentiates it from Stage IV disease, when the cancer has spread (metastasised) to distant organs.

The majority of Stage III NSCLC patients are diagnosed with unresectable tumours. Until now, the current standard of care has been chemotherapy and radiation therapy, followed by active surveillance to monitor for progression. The prognosis remains poor and long-term survival rates are low.

Urothelial cancer makes up more than 90% of all bladder cancer cases and affects several parts of the urinary tract, including the renal pelvis, ureters, bladder and urethra. Urothelial cancer is one of the most common urological malignancies(4).

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

AstraZeneca Pharma India Limited

AstraZeneca has a long history and a strong footprint in India. This year, AstraZeneca will celebrate its 40th business anniversary in India. AstraZeneca Pharma India Limited, a listed company, established in 1979 and headquartered in Bengaluru, Karnataka has a workforce of over 1200 employees and is the operating company covering manufacturing, sales and marketing activities. It

has an innovative portfolio to address the unmet needs in non-communicable diseases such as diabetes, heart disease, cancer, asthma and COPD. For more information, please visit www.astrazeneca.com/india

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References:

1. American Cancer Society. What Is Non-Small Cell Lung Cancer? Available at <https://www.cancer.org/cancer/non-small-cell-lung-cancer/about/what-is-non-small-cell-lung-cancer.html>. Accessed on 21st June, 2018.
2. Digambar Behera. Lung Cancer in India: Challenges and Perspectives. *Journal of Thoracic Oncology*. January 2017 Volume 12, Issue 1, Supplement, Pages S114–S115.
3. Murali AN, Radhakrishnan V, Ganesan TS, et al. Outcomes in Lung Cancer: 9-Year Experience From a Tertiary Cancer Center in India. *Journal of Global Oncology*. 2017;3(5):459-468. doi:10.1200/JGO.2016.006676.
4. Gupta P, Jain M, Kapoor R, Muruganandham K, Srivastava A, Mandhani A. Impact of age and gender on the clinicopathological characteristics of bladder cancer. *Indian Journal of Urology : IJU : Journal of the Urological Society of India*. 2009;25(2):207-210. doi:10.4103/0970-1591.52916.