PRESS RELEASE

FOR IMMEDIATE RELEASE:

EXKIVITY® (mobocertinib) Approved for Previously-Treated Adult Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer with Epidermal Growth Factor Receptor Exon 20 Insertion Mutations

Louisville, Ky. — September 17, 2021 — Onco360®, the nation's largest independent Oncology Pharmacy, has been selected by Takeda to be a specialty pharmacy partner for EXKIVITY® (mobocertinib), the first oral treatment option for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

"Onco360 is excited to become a specialty pharmacy provider for EXKIVITY patients," said Benito Fernandez, Chief Commercial Officer, Onco360. "As a provider of this important treatment option for patients, Onco360 is committed to supporting the highly specialized needs of locally advanced or metastatic NSCLC patients with EGFR exon 20 insertion mutations and their physicians across the United States."

According to the National Cancer Institute's (NCI) Surveillance, Epidemiology, and End Results (SEER) Program, approximately 235,760 patients will be diagnosed with lung cancer in 2021 with a corresponding 131,880 deaths. Approximately 85% of lung cancer cases are represented by NSCLC. When considering all subtypes of lung cancer as well as stages of the disease, lung cancer patients have a poor five-year overall survival (OS) of 21.7%. Unfortunately, 56% of lung cancer patients will have incurable, metastatic disease at the time of initial diagnosis.[1] Approximately 0.1 to 4% of all NSCLC patients have EGFR exon 20 insertion mutations.[2]

EXKIVITY is manufactured by Takeda, a commercial-stage biotechnology company. The FDA's approval of EXKIVITY is based upon the results of a pooled subset of patients with EGFR exon 20 insertion mutation-positive locally advanced or metastatic NSCLC whose disease had progressed on or after platinum-based chemotherapy who were enrolled in the international, open-label, multicohort Phase I/II AP32788-15-101 (NCT02716116) clinical trial. This data demonstrated that EXKIVITY administration resulted in a 28% overall response rate (ORR) in this patient population.[3] For full prescribing information, visit EXKIVITY.com.

About Onco360® Oncology Pharmacy:
Onco360 is the largest independent Oncology Pharmacy and clinical support services company in the country. Onco360 was founded in 2003 to bring together the stakeholders involved in the cancer treatment process and serve the specialized needs of oncologists, patients, hospitals, cancer centers of excellence, manufacturers, health plans, and payers. It dispenses nationally through its network of URAC-, and ACHC-accredited Oncology Pharmacies. Onco360 is headquartered in Louisville, Kentucky, and is a flagship specialty pharmacy brand of PharMerica Corporation, a leading institutional pharmacy, specialty infusion, and hospital services company servicing healthcare facilities in the United States. For more information about Onco360, please visit Onco360.com.

Media Contact:
Benito Fernandez, Chief Commercial Officer
benito.fernandez@onco360.com
516-640-1332

References:

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2) Burnett H, Emich H, Carroll C, Stapleton N, Mahadevia P, Li T. Epidemiological and clinical burden of EGFR Exon 20 insertion in advanced non-small cell lung cancer: A systematic literature review. PLoS One. 2021;16(3):e0247620.
3) Exkivity Prescribing Information. Available at exkivity.com. Accessed September 2021.