Exkivity® (mobocertinib) – Drug withdrawal

- On October 2, 2023, Takeda announced the voluntary withdrawal of Exkivity (mobocertinib), for the treatment of 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.

- Exkivity remains available to prescribe while Takeda works with the FDA on withdrawal timing. Takeda will provide updates when and as appropriate. Takeda is committed to ensuring that patients receiving Exkivity can maintain access when Exkivity is withdrawn.

Product Description	NDC Number
Exkivity (mobocertinib) 40 mg	Bottle of 90 capsules: 63020-040-90; Bottle of 120 capsules: 63020-040-12

- Exkivity was granted FDA approval under the accelerated approval pathway in September 2021.

- Full approval was contingent upon demonstration of clinical benefit in the confirmatory phase 3 EXLAIM-2 study. This study did not meet its primary endpoint and thus did not fulfill the confirmatory data requirements of the accelerated approval granted.

- Takeda will work with the FDA to complete the withdrawal process and notify healthcare professionals about this withdrawal.

- Patients currently being treated with Exkivity should consult their healthcare provider.

- For additional questions, please contact Takeda at **1-844-662-8532** or **globaloncologymedinfo@takeda.com**.