

NCCN Non-Small Cell Lung Cancer v.6.2021 – Follow-up – September 19, 2021

Guideline Page and Request	Panel Discussion/References	Institution Vote			
		YES	NO	ABSTAIN	ABSENT
<p>NSCL-23/NSCL-J <u>Internal request:</u> Evaluate the data supporting mobocertinib as a subsequent therapy option for patients (PS 0-2) with advanced or metastatic NSCLC with <i>EGFR exon 20</i> insertion mutations, whose disease has progressed on or after initial systemic therapy options (NSCL-K 1 of 5, NSCL-K 2 of 5).</p> <p><u>External request:</u> Submission from Takeda, requesting the following changes:</p> <ul style="list-style-type: none"> NSCL-18: “Biomarker Testing” For both “Adenocarcinoma/Large Cell/NSCLC NOS” and “Squamous Cell Carcinoma Cell”: Include “EGFR exon 20 insertion mutations” as a recommended molecular test NSCL-19: “Testing Results” Add a new algorithm page for “EGFR Exon20 Insertion-Positive”: add “Mobocertinib” NSCL-H2: “Principles of Molecular and Biomarker Analysis” Under the subsection beginning “EGFR exon 20 insertion (EGFRex20ins) mutations...”: <ul style="list-style-type: none"> Include statement “Mobocertinib is a first-in-class, oral tyrosine kinase inhibitor specifically designed to target EGFR exon20 insertion mutations. Responses occurred across all identified EGFRex20ins variant mutation subtypes.” Include statement: “NGS is preferred as PCR can potentially miss EGFRex20ins.” NSCL-J1: “Targeted Therapy or Immunotherapy for Advanced or Metastatic Disease” Under a new category “EGFR Exon 20 Insertion-Positive”: Add “Mobocertinib” 	<p>Based on the data in the noted references, the Panel consensus supported the addition of mobocertinib as a subsequent therapy option for patients (PS 0-2) with advanced or metastatic NSCLC with <i>EGFR exon 20</i> insertion mutations, whose disease has progressed on or after initial systemic therapy options (NSCL-K 1 of 5, NSCL-K 2 of 5). This is a category 2A recommendation.</p> <ul style="list-style-type: none"> Ramalingam SS, Zhou C, Kim TM, et al. Mobocertinib (TAK-788) in EGFR exon 20 insertion (ex20ins)+ metastatic NSCLC (mNSCLC): Additional results from platinum-pretreated patients (pts) and EXCLAIM cohort of phase 1/2 study [abstract]. J Clin Oncol 2021;39:9014-9014. See Submission for references. 	19	1	2	9