

# Treatment patterns and clinical outcomes among advanced NSCLC patients with *EGFR* exon 20 insertion mutations in China

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Background
<ul style="list-style-type: none"><li>In China, lung cancer is also the most common cancer with the incidence rate of 59.89 per 100,000 populations, leading to most cancer deaths with the mortality rate of 47.51 per 100,000 populations <sup>1,2</sup></li><li>Epidermal growth factor receptor (<i>EGFR</i>) is among the most important genes in non-small cell lung cancer (NSCLC), particularly in Asian populations where it is prevalent in up to 50% of patients <sup>3,4</sup></li><li>NSCLC patients with <i>EGFR</i> exon 20 insertion mutations (ex20Ins) have a poor prognosis with median overall survival ranging from 16.5 – 17.8 months <sup>5,6,7</sup></li><li>Mobocertinib is approved by FDA as the first oral therapy specifically designed for NSCLC patients with ex20Ins, and was recently approved by the China's National Medical Products Administration (NMPA) in 2023 <sup>8,9</sup></li><li>There are very few studies on real-world clinical efficacy and safety of available treatments and the unmet needs for NSCLC patients with ex20Ins in China</li></ul>
Methods
<b>Patient sample</b> <ul style="list-style-type: none"><li>Inclusion criteria<ul style="list-style-type: none"><li>Patients aged ≥ 18 years at advanced NSCLC diagnosis</li><li>Had a pathologically and/or cytologically confirmed diagnosis of stage IIIB/IV NSCLC prior to June 1, 2019 (either primary or after relapse of initial non-metastatic disease)</li><li>Had a detection of an ex20Ins through genomic sequencing</li><li>Had documentation available for at least two visits</li></ul></li><li>Patient sampling<ul style="list-style-type: none"><li>All eligible patients were consecutively entered into the study starting from the months prior to June 1, 2019</li><li>Enrolling consecutive eligible patients in each month prior to June 2019</li><li>Patients were followed from the diagnosis to the end of data availability or end of the study period (Jan 2022), whichever came first</li></ul></li></ul>
<b>Study outcomes</b> <ul style="list-style-type: none"><li>Patient demographics, clinical characteristics, and treatment patterns</li><li>Real-world progression-free survival (PFS) for each line of therapy (LOT)</li><li>Confirmed objective response rates (ORR): defined as percentages of patients with 2 complete responses (CRs) or partial responses (PRs), as confirmed by the study lead clinicians</li></ul>
<b>Statistical analysis</b> <ul style="list-style-type: none"><li>Descriptive analyses were conducted to describe patient demographics and clinical characteristics, treatment patterns, and clinical outcomes</li><li>Kaplan-Meier analyses were performed to estimate real-world PFS for each LOT</li></ul>
Results
<b>Demographic and clinical characteristics (Table 1)</b> <ul style="list-style-type: none"><li>116 patients were included: 70 patients from SPH and 46 from CICAMS</li><li>Average age of patients was 56.2 years (range 27.8 to 76.1)</li><li>46.6% were women</li><li>58.6% had intrathoracic metastases and 30.2% had brain metastases</li></ul>
<b>References</b> <div>1. Siegel et al. CA Cancer J Clin. 2023;73(1):17-48 2. Zheng et al. Zhonghua Zhong Liu Za Zhi. 2023;45(3):212-220 3. Pi et al. Thorac Cancer. 2018;9(7):814-819 4. Zhang et al. Transl Lung Cancer Res. 2019;8(3):302-316 5. Yang et al. Lung Cancer. 2021;152:39-48 6. Ou et al. American Society of Clinical Oncology. 2021 7. Christopoulos et al. European Lung Cancer Virtual Congress. 2021 8. Mobocertinib Approved by U.S. FDA. 2021 9. Mobocertinib Approved by China NMPA, 2023</div>

Study objective	To evaluate real-world data on treatment patterns and clinical outcomes for advanced non-small cell lung cancer (NSCLC) patients with epidermal growth factor receptor ( <i>EGFR</i> ) exon 20 Insertion mutations (ex20Ins) in China																																						
Study design	<b>A retrospective chart review study was undertaken at 2 large state-level cancer hospitals in China:</b> <ul style="list-style-type: none"><li>Shanghai Pulmonary Hospital (SPH)</li><li>Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College in Beijing (CICAMS)</li></ul>																																						
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<b>Treatment characteristics and Clinical outcomes</b> <ul style="list-style-type: none"><li>All patients received 1st line of therapy (LOT)<ul style="list-style-type: none"><li>99 (85.3%) patients initiated 1st line platinum-based chemotherapy</li><li>3 (2.6%) patients initiated EGFR tyrosine kinase inhibitors (TKIs)</li></ul></li><li>Among patients who received platinum-based chemotherapy as 1st LOT (N=99), only 59.6% of patients continued with 2nd LOT (N=59)</li><li>Kaplan-Meier analyses showed<ul style="list-style-type: none"><li>Median real-world PFS of 1st LOT was 6.2 months</li><li>Median real-world PFS of 2nd LOT was 4.2 months for patients with post platinum-based treatments</li></ul></li><li>Confirmed objective response rates<ul style="list-style-type: none"><li>14.8% (N=13) for patients with 1st LOT</li><li>10.0% (N=3) for patients with post-platinum 2nd LOT</li></ul></li></ul>	<div><div>Figure 1. Real-world PFS of 1st LOT (N=116)</div></div> <div><div>Figure 2. Real-world PFS of 2nd LOT for patients who used platinum therapy as 1st LOT (N=59)</div></div>																																						
Key Take Aways	<ul style="list-style-type: none"><li>This study evaluated previous treatment patterns and clinical outcomes for advanced NSCLC patients with ex20Ins in China, addressing a critical gap in existing knowledge of those patients in real-world</li><li>The findings of this study revealed that the prognosis of advanced NSCLC patients with <i>EGFR</i> ex20ins in China was poor, highlighting the unmet need for novel therapies in this patient population</li><li>Future real-world data are warranted to evaluate the effectiveness of approved novel target therapy in China</li></ul>																																						
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<b>Strengths of the study</b> <ul style="list-style-type: none"><li>The study was conducted in two large state-level hospitals, ensuring that the findings are representative of the advanced NSCLC patient population with <i>EGFR</i> ex20ins in China, given the hospitals' extensive medical background and patient behaviors</li><li>The study employed robust and validated methods to efficiently collect retrospective data, leveraging the best available data sources in China</li></ul>																																							
<b>Limitations of the study</b> <ul style="list-style-type: none"><li>The study relied solely on data recorded in medical records, which may have resulted in missing data</li><li>Complete death information was lacking from the current medical charts in China, which could have impacted the assessment of clinical outcomes</li><li>Due to the nature of a chart review study, all clinical outcomes are subject to potential measurement errors</li></ul>																																							
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