



Mobocertinib for Patients with EGFR Exon 20 Insertion-Positive Metastatic NSCLC with Disease Progression on Prior EGFR TKI Therapy



Marcia K. Horn, JD, Executive Director, the Exon 20 Group and CEO, ICAN, International Cancer Advocacy Network

In reference to: OA15.01 “Mobocertinib in EGFR Exon 20 Insertion-Positive Metastatic NSCLC Patients With Disease Control on Prior EGFR TKI Therapy” presented by Dr. Alexander I. Spira

The Exon 20 Group has worked with patients on mobocertinib (formerly known as TAK-788) since 2017. We look forward to the U.S. Food and Drug Administration’s approval of this Breakthrough Therapy-designated EGFR tyrosine kinase inhibitor (TKI) in the coming months. Alexander I. Spira, MD, PhD, of Virginia Cancer Specialists and US Oncology Research, Fairfax, Virginia, who is one of the leading experts on drugs in the exon 20 space, presented the phase II expansion data from the phase I/II mobocertinib trial focusing on Cohort 5 for patients with refractory EGFR exon20 insertions whose disease progressed after an objective response or stable disease for 6 months or more on any prior EGFR TKI compound.

The toxicity burden appears manageable. Although adverse events associated with 160 mg of mobocertinib once daily included diarrhea, nausea, pruritus, rash, anemia, vomiting, fatigue, only two out of 20 patients discontinued the drug because of adverse events. The safety profile comports with what we typically see for other EGFR TKIs.

Twenty patients had prior EGFR TKI therapy: 13 had poziotinib, four had osimertinib; four had afatinib, two had erlotinib, and one had an investigational TKI. Data cut-off was November 1, 2020, and 35% of patients who had received prior TKIs remained on mobocertinib, with a median time on treatment of 7.8 months. A confirmed overall response rate was found for 31% of patients pretreated with poziotinib and 50% of patients pretreated with osimertinib. With a confirmed disease control rate per investigator of 90%, an overall response rate of 40%, a median duration of response of 13.0 months, and median progression-free survival of 7.3 months, this drug merits quick approval. These Cohort 5 data underscore how important this drug will continue to be for patients who have had disease progression on prior TKIs.



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