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FDA Grants Breakthrough Therapy Designation to JNJ-6372 in mNSCLC

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The FDA granted Breakthrough Therapy designation to JNJ-61186372 (JNJ-6372) for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with *EGFR* exon 20 insertion mutation whose disease has progressed on or after platinum-based chemotherapy, Janssen Pharmaceuticals, developer of the agent, announced in a press release.

This Breakthrough Therapy designation is supported by results from a phase I, first-in-human study of JNJ-61186372, *EGFR MET* bispecific antibody, administered at different doses to evaluate the safety, pharmacokinetics and preliminary efficacy of the agents as monotherapy and in combination with novel third generation EGFR tyrosine kinase inhibitor (TKI) lazeritinib in adults with advanced NSCLC.

The open-label, dose escalation study includes 2 experimental cohorts in which patients received JNJ-6118637 at 140 mg intravenously as monotherapy in part 1. Lazeritinib is administered in combination with JNJ-6118637 in part 1 based on observed safety and protocol defined criteria, daily on the 28-day treatment cycle. In part 2, patients received the doses of JNJ-6118637 plus lazeritinib determined in part 1.

The primary end point of part 1 was the number of participants with a dose-limiting toxicity. In part 2, the coprimary end points included the number of participants with an adverse event (AE) or serious AE, overall response rate, duration of response, and the percentage of patients with clinical benefit. The key secondary end points were maximum serum concentration, time to reach maximum observed serum concentration, progression-free survival, time to treatment failure, and overall survival.

Patients were eligible to join the study if they had a histologically or cytologically confirmed diagnosis of NSCLC that was metastatic or unresectable. Patients were required to have an ECOG performance status of 0 or 1. The study excluded individuals with certain comorbidities that may have interfered with treatment, as well as those with untreated brain metastases, locally-treated metastases that were clinically stable and asymptomatic for at least 2 weeks. Patients with a history of another malignancy with 3 years before the study's screening period were also excluded.

"JNJ-6372 is a novel bispecific antibody that we believe has the potential to benefit patients with exon 20 mutation insertions who often do not respond to currently available oral EGFR-targeted or immune checkpoint inhibitor therapies," said Peter Lebowitz, MD, PhD, global therapeutic area head, Oncology, Janssen Research & Development, LLC. "This Breakthrough Therapy Designation is a significant milestone in our ongoing efforts to

advance JNJ-6372 in clinical development and target genetically-defined lung cancer.”

Reference:

Janssen announces U.S. FDA breakthrough therapy designation granted for jnj-6372 for the treatment of non-small cell lung cancer [news release]. Raritan, New Jersey: The Janssen Pharmaceutical Companies of Johnson & Johnson; March 10, 2020. https://prn.to/2IDJQJv. Accessed March 10, 2020.

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