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Novartis phase II GEOMETRY *mono-1* trial of investigational medicine capmatinib (INC280) shows positive results in patients with MET mutated advanced NSCLC

- *Phase II study efficacy data showed overall response rate of 72.0% and 39.1%, respectively, in treatment-naive and previously treated patients with advanced MET exon-14 skipping mutated non-small cell lung cancer (NSCLC)*

- *Clinical findings from ongoing study indicate safety profile was consistent with previously reported data results*

- *Capmatinib, an investigational MET inhibitor, may have the potential to improve response rates for people diagnosed with MET exon-14 skipping mutated NSCLC, a known oncogenic driver*

Basel, October 19, 2018 – Novartis today announced Phase II preliminary results of the GEOMETRY *mono-1* clinical trial of investigational MET inhibitor capmatinib (INC280) in 94 adult patients with advanced non-small cell lung cancer (NSCLC) harboring MET exon-14 skipping mutations. The GEOMETRY *mono-1* study showed an overall response rate (ORR) of 72.0% (95% CI: 50.6-87.9) in treatment-naive patients and 39.1% (95% CI: 27.6-51.6) in previously treated patients. ORR was assessed by blinded independent review committee (BIRC). Adverse events (AEs) were consistent with previously reported data and no new safety signals were observed. Results of the Phase II study were presented today at the European Society for Medical Oncology (ESMO) 2018 Congress [October 19, 2018 at 4:45 PM CET] (Abstract #LBA52)[1].

“These preliminary findings reveal the potential of capmatinib in MET exon-14 skipping mutated NSCLC patients. Compared to the previously treated patient groups, the primary advantage in terms of overall response rate reported in treatment-naive patients highlights the clinical relevance for an earlier diagnostic testing and prompt treatment of this challenging patient population,” said Juergen Wolf, MD, University Hospital Cologne.

NSCLC is the most common type of lung cancer, impacting more than 2 million people per year[2]. Approximately 3-4% of all patients with NSCLC have an identified MET mutation[3]. Though rare, this mutation is an indicator of especially poor prognosis and there is currently no approved therapy designed to target this mutation[4].

“Patients diagnosed with advanced MET mutated NSCLC represent an unmet medical need and often face a poor prognosis,” said Samit Hirawat, MD, Head, Novartis Oncology Global Drug Development. “We are encouraged by the GEOMETRY *mono-1* results and the potential for capmatinib to help patients with this disease.”

About GEOMETRY *mono-1*
The GEOMETRY *mono-1* trial is a multicenter, open-label, phase II study to evaluate the efficacy and safety of single-agent INC280 in adult patients with EGFR wildtype, ALK-negative rearrangement, advanced NSCLC harboring MET amplification and/or mutations. Patients with MET exon-14 skipping were assigned to Cohorts 4 (previously treated patients) or 5B

(treatment naive) regardless of MET amplification/gene copy number (centrally confirmed), and received 400 mg capmatinib tablets twice daily. The primary endpoint was ORR based on BIRC assessment per RECIST v1.1. The key secondary endpoint was duration of response (DOR) by BIRC. The GEOMETRY *mono-1* study found an ORR in the treatment-naive patients (n=25) of 72.0% (95% CI: 50.6-87.9) and an ORR in the previously treated patients (n=69) of 39.1% (95% CI: 27.6-51.6). DOR was not reached by the time of analysis, indicating sustainability of response[1,6].

The most common treatment-related AEs included peripheral edema, nausea, vomiting, and increased blood creatinine levels. Of patients treated with INC280, 83.8% experienced an AE, with 33.1% having grade 3/4 AEs[1,6].

Capmatinib (INC280) is an investigational, oral and selective MET inhibitor licensed to Novartis by Incyte Corporation in 2009. Under the Agreement, Incyte granted Novartis exclusive Development and Commercialization worldwide rights to this MET inhibitor compound and certain back-up compounds in all indications.

Novartis Commitment to Lung Cancer
Worldwide, lung cancer causes more deaths than colon, breast and prostate cancer combined, and over 2 million new cases of lung cancer are diagnosed each year[2]. Among patients with NSCLC, almost 70% have an actionable mutation that may be targeted with available therapies[7]. To determine the most appropriate treatment, medical organizations recommend genomic testing for patients with lung cancer[8].

Novartis Oncology's research in NSCLC has helped transform treatment approaches for patients living with mutation-driven diseases, among others. Novartis continues its commitment to the global lung cancer community through ongoing studies, as well as the exploration of investigational compounds that target genetic biomarkers in NSCLC.

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