



Phase 2 GEOMETRY mono-1 Trial of Investigational Medicine Capmatinib Shows Positive Results in Patients with MET-mutated Advanced NSCLC

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- Phase 2 study efficacy data showed overall response rate of 72.0 percent and 39.1 percent, respectively, in treatment-naïve 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
- Novartis has exclusive development and commercialization worldwide rights to capmatinib

WILMINGTON, Del.--(BUSINESS WIRE)--Oct. 19, 2018-- Incyte (NASDAQ:INCY) today announced Phase 2 preliminary results of the GEOMETRY *mono-1* clinical trial of investigational MET inhibitor capmatinib 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 percent (95% CI: 50.6-87.9) in treatment-naïve patients and 39.1 percent (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 Novartis-sponsored Phase 2 study were presented today at the European Society for Medical Oncology (ESMO) 2018 Congress (October 19, 2018 at 4:45 p.m. CEST / 10:45 a.m. EDT, 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-naïve patients highlights the clinical relevance for an earlier diagnostic testing and prompt treatment of this challenging patient population," said Juergen Wolf, M.D., University Hospital Cologne, Germany.

NSCLC is the most common type of lung cancer, impacting more than 2 million people per year.² Approximately 3-4 percent 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

"We are very pleased to announce these promising, preliminary results for capmatinib, another investigational medicine invented at Incyte that has the potential to be the first MET-selective targeted agent approved by the FDA," said Steven Stein, M.D., Chief Medical Officer, Incyte. "We are encouraged by the results of this study and the potential for capmatinib to help patients with advanced MET mutated NSCLC, who face a poor prognosis and represent a clear unmet medical need."

About GEOMETRY *mono-1*

The GEOMETRY *mono-1* trial is a multicenter, open-label, Phase 2 study to evaluate the efficacy and safety of single-agent capmatinib (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 naïve) 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-naïve patients (n=25) of 72.0 percent (95% CI: 50.6-87.9) and an ORR in the previously treated patients (n=69) of 39.1 percent (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 capmatinib, 83.8 percent experienced an AE, with 33.1 percent having grade 3/4 AEs.^{1,6}

About Capmatinib

Capmatinib (INC280) is an investigational, oral and selective MET inhibitor invented at Incyte that was licensed to Novartis 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 has stated that it expects to submit a new drug application to the U.S. Food and Drug Administration for capmatinib as a treatment for patients with advanced non-small cell lung cancer (NSCLC) harboring MET amplification and/or mutations in 2019. If capmatinib is successfully developed by Novartis, Incyte may become eligible for over \$500 million in future milestones as well as royalties of between 12 percent and 14 percent on global sales by Novartis.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit the Company's website at www.incyte.com.

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Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the ongoing clinical development program for capmatinib and its potential in treating NSCLC, Novartis' plans to file an NDA for capmatinib and the expected timing of such filing, and whether and when Incyte may receive milestone payments or royalties from Novartis relating to capmatinib, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; determinations made by the FDA; the Company's dependence on its relationships with its collaboration partners; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; greater than expected expenses; expenses relating to litigation or strategic activities; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended June 30, 2018. The Company disclaims any intent or obligation to update these forward-looking statements.

References

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3. Salgia R. MET in Lung Cancer: Biomarker Selection Based on Scientific Rationale. *Mol Cancer Ther.* 2017;16(4):555-565.
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