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New Data from GEOMETRY mono-1 Study Show Clinically Meaningful Results in Patients with Non-Small Cell Lung Cancer with MET exon-14 Skipping Mutation Treated with Capmatinib

June 3, 2019

- *Primary efficacy analysis demonstrated promising efficacy for capmatinib irrespective of the prior line of therapy in 97 patients: overall response rate was 68 percent and 41 percent and median duration of response was 11.14 months and 9.72 months, respectively, across treatment-naïve and previously-treated patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring a MET exon-14 skipping mutation*
- *The U.S. Food and Drug Administration recently granted capmatinib Breakthrough Therapy designation for the treatment of patients with metastatic NSCLC harboring a MET exon-14 skipping mutation with disease progression on or after platinum-based chemotherapy*
- *Novartis has exclusive worldwide development and commercialization rights to capmatinib*

WILMINGTON, Del.--(BUSINESS WIRE)--Jun. 3, 2019-- Incyte (Nasdaq:INCY) today announced primary efficacy results from the Novartis-sponsored GEOMETRY *mono-1* Phase 2 clinical trial of capmatinib, an investigational, selective MET inhibitor. The results demonstrate that capmatinib shows promise as a potential treatment option for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that harbor a MET exon-14 skipping mutation. There are currently no approved targeted therapies to treat this particularly aggressive form of NSCLC.

Results of the Phase 2 study will be presented at an oral session today, June 3, 2019, at the American Society of Clinical Oncology (ASCO) 2019 Annual Meeting at 8:00 a.m. CDT (Abstract #9004)¹.

GEOMETRY *mono-1* is an international, prospective, multi-cohort, non-randomized, open-label study evaluating 97 adult patients with locally advanced or metastatic NSCLC harboring a MET exon-14 skipping mutation who received capmatinib tablets 400 mg orally twice daily. Primary efficacy results among treatment-naïve patients (Cohort 5b: 28 patients) included a 68 percent overall response rate (ORR) based on the Blinded Independent Review Committee (BIRC) assessment per RECIST v1.1 (95% CI: [47.6-84.1]) and 41 percent of previously-treated NSCLC patients (Cohort 4: 69 patients) also responded (95% CI: [28.9 - 53.1]). Data on median duration of response (DOR), a key secondary endpoint, was 11.14 months (95% CI: [5.55-NE]) and 9.72 months (95% CI: [5.55-12.98]), in the treatment-naïve and previously-treated groups, respectively. Intracranial activity in 54 percent (n=7/13) of patients, including some cases of complete resolution of brain lesions, was also observed by ad hoc neuro-radiologist review in patients with brain lesions. All results were based on independent assessment by the BIRC, and all tumor CT scans were evaluated in parallel by two radiologists to confirm the response.

The most common treatment-related adverse events (AE) (≥10% all grades) across all cohorts (n=334), were peripheral edema (42%), nausea (33%), creatinine increase (20%), vomiting (19%), fatigue (14%), decreased appetite (13%) and diarrhea (11%); the majority of the AEs were grades 1/2.

"In the absence of approved targeted therapies, patients with advanced or metastatic NSCLC harboring a MET exon-14 skipping mutation must rely on existing treatment approaches and, as a result, face a particularly poor prognosis," said Steven Stein, M.D., Chief Medical Officer, Incyte. "The results of the GEOMETRY *mono-1* study to be presented at ASCO underscore the potential of capmatinib to meaningfully improve outcomes for this underserved subset of NSCLC patients."

The U.S. Food and Drug Administration (FDA) recently granted capmatinib Breakthrough Therapy designation for patients with metastatic NSCLC harboring a MET exon-14 skipping mutation with disease progression on or after platinum-based chemotherapy. Previously, both the U.S. FDA and Japan's Pharmaceuticals and Medical Devices Agency recognized capmatinib with Orphan Drug status. It is estimated that 3 to 4 percent of all patients with NSCLC have an identified MET mutation².

Novartis expects to submit a new drug application to the FDA for capmatinib as a treatment for patients with advanced NSCLC harboring a MET mutation in 2019.

About GEOMETRY *mono-1*

The Novartis-sponsored GEOMETRY *mono-1* trial is an international, prospective, multi-cohort, non-randomized, open-label Phase 2 study to evaluate the efficacy and safety of single-agent capmatinib in adult patients with EGFR wildtype, ALK-negative rearrangement, advanced NSCLC harboring a MET amplification and/or mutation. Patients with locally advanced or metastatic NSCLC harboring a MET exon-14 skipping mutation (centrally confirmed) were assigned to Cohorts 4 (previously treated patients) or 5B (treatment-naïve), regardless of MET amplification/gene copy number and received 400 mg capmatinib tablets orally twice daily.

The primary endpoint was ORR based on BIRC assessment per RECIST v1.1. The key secondary endpoint was DOR by BIRC. The GEOMETRY *mono-1* study found an ORR in the treatment-naïve patients (n=28) of 67.9 percent (95% CI: [47.6 - 84.1]) and an ORR of 40.6 % (95% CI: [28.9 - 53.1]) in the previously treated patients (n=69). Median DOR was 11.14 months (95% CI: [5.55-NE]) in treatment-naïve patients and 9.72 months (95% CI: [5.55-12.98]) in previously treated patients¹.

The most common treatment-related AEs included peripheral edema, nausea, creatinine increase and vomiting. Of patients treated with capmatinib, 84 percent experienced an AE, with 36 percent having grade 3/4 AEs (only 4.5% were Grade 4)¹.

About Capmatinib

Capmatinib is an investigational, oral and selective MET inhibitor discovered by Incyte that was licensed to Novartis in 2009. Under the terms of the Agreement, Incyte granted Novartis exclusive worldwide development and commercialization rights to capmatinib and certain back-up compounds in all indications. 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 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 submit 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 and the risks related to the efficacy or safety of the Company's development pipeline, the results of further research and development, the high degree of risk and uncertainty associated with drug development, clinical trials and regulatory approval processes, other market or economic factors and competitive and technological advances; 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 ending March 31, 2019. Incyte disclaims any intent or obligation to update these forward-looking statements.

References

1. Juergen Wolf. Capmatinib (INC280) in *METΔex14*-mutated advanced non-small cell lung cancer (NSCLC): efficacy data from the Phase 2 GEOMETRY *mono-1* study. Abstract #9004. 2019 American Society of Clinical Oncology Annual Meeting (ASCO), May 31-June 4, 2019, Chicago, IL.
2. Salgia R. MET in Lung Cancer: Biomarker Selection Based on Scientific Rationale. *Mol Cancer Ther.* 2017;16(4):555-565.



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