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Novartis announces MET inhibitor capmatinib (INC280), the first potential treatment for METex14 mutated advanced non-small cell lung cancer, granted priority FDA review

- *FDA Priority Review for capmatinib based on Phase II data in first-line and previously treated patients with MET exon 14 skipping (METex14) mutated advanced non-small cell lung cancer (NSCLC)*[1]

- *Substantial unmet need exists among patients with METex14 mutated advanced NSCLC as there are no treatment options approved to specifically target this aggressive form of lung cancer*

- *Capmatinib review expected to be completed within six months*

Basel, February 11, 2020 — Novartis announced today that the US Food and Drug Administration (FDA) accepted and granted Priority Review to capmatinib's (INC280) New Drug Application (NDA). Capmatinib is a MET inhibitor being evaluated as a treatment for first-line and previously treated patients with locally advanced or metastatic MET exon 14 skipping (METex14) mutated non-small cell lung cancer (NSCLC). If approved, capmatinib will be the first therapy to specifically target METex14 mutated advanced lung cancer, a type of lung cancer with a particularly poor prognosis[2,3].

Priority Review is granted to therapies that the FDA determines have the potential to provide significant improvements in the treatment, diagnosis or prevention of serious conditions. This designation shortens the FDA review period following the acceptance of the NDA to six months compared to ten months under Standard Review. Novartis was previously granted Breakthrough Therapy designation for capmatinib.

There are currently no approved therapies that specifically target METex14 mutated advanced NSCLC. NSCLC accounts for approximately 85% of lung cancer diagnoses[4]. METex14 mutations occur in 3-4% of newly diagnosed advanced NSCLC cases[5] and is a recognized oncogenic driver[6,7]. As part of the continued collaboration between Novartis and Foundation Medicine, Inc., companion diagnostics for capmatinib are in development for both tumor tissue and liquid biopsies to be included on FoundationOne®CDx* and the forthcoming version of Foundation Medicine's liquid biopsy platform, which is currently under review with the FDA. Foundation Medicine is a leading provider of comprehensive genomic profiling solutions for patients with advanced cancer, including NSCLC.

"We are extremely encouraged by the FDA's Priority Review designation for capmatinib, a MET inhibitor that may be a major treatment advance for patients with this particularly aggressive form of lung cancer," said John Tsai, M.D., Head of Global Drug Development and Chief Medical Officer, Novartis. "Results of the GEOMETRY *mono*-1 trial clearly identify

METex14 as an oncogenic driver and we are inspired to bring capmatinib, potentially the first METex14 targeted therapy, to patients and to reimagine medicine and outcomes for people with lung cancer."

The NDA submission for capmatinib is supported by results from the GEOMETRY *mono*-1 Phase II study, which demonstrated an overall response rate of 67.9% (95% CI, 47.6 - 84.1)[1] and 40.6% (95% CI, 28.9 - 53.1)[1] among treatment-naïve and previously treated patients, respectively, based on the Blinded Independent Review Committee (BIRC) assessment per RECIST v1.1. The study also demonstrated that capmatinib provided durable responses among all patients: median duration of response 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 patients[1].

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[1]. 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[1].

About Lung Cancer
Lung cancer is the most common cancer worldwide, accounting for 2.1 million new cases and 1.8 million deaths in 2018[8]. There are two main types of lung cancer – small cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC)[9]. NSCLC accounts for approximately 85% of lung cancer diagnoses, inclusive of known oncogenic mutations[4]. The MET exon 14 skipping mutation occurs in 3-4% of newly diagnosed advanced NSCLC cases[5]. There are currently no approved therapies specifically targeted to treat METex14 mutated advanced lung cancer.

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

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This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "may," "could," "would," "expect," "anticipate," "seek," "look forward," "believe," "committed," "investigational," "pipeline," "launch," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of

physicians and patients; general political and economic conditions; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis
Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach more than 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109,000 people of more than 145 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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References

1. Juergen Wolf. Capmatinib (INC280) in METΔex14-mutated advanced non-small cell lung cancer (NSCLC): efficacy data from the Phase II GEOMETRY mono-1 study. Abstract #9004. 2019 American Society of Clinical Oncology Annual Meeting (ASCO), May 31-June 4, 2019, Chicago, IL.
2. Cappuzzo F, et al. Increased MET gene copy number negatively affects survival of surgically resected non-small-cell lung cancer patients. J Clin Oncol 2009;27:1667-74.
3. Tong JH, et al. MET Amplification and Exon 14 Splice Site Mutation Define Unique Molecular Subgroups of Non-Small Cell Lung Carcinoma with Poor Prognosis. Clin Cancer Res 2016;22:3048-56.
4. American Cancer Society. About Lung Cancer. Available at https://www.cancer.org/cancer/non-small-cell-lung-cancer/about/what-is-non-small-cell-lung-cancer.html. Accessed December 13, 2019.
5. Salgia R. MET in Lung Cancer: Biomarker Selection Based on Scientific Rationale. Mol Cancer Ther. 2017;16(4):555-565.
6. Sadiq AA, Salgia R. MET as a possible target for non-small-cell lung cancer. J Clin Oncol 2013;31:1089-96.
7. Smyth EC, et al. Emerging molecular targets in oncology: clinical potential of MET/hepatocyte growth-factor inhibitors. Onco Targets Ther. 2014;7:1001-1014.
8. World Health Organization. Cancer Fact Sheet, 2018. Available at: https://www.who.int/news-room/fact-sheets/detail/cancer. Accessed December 13, 2019.
9. CancerCare. Types and Staging of Lung Cancer. Available at: https://www.lungcancer.org/find_information/publications/163-lung_cancer_101/268-types_and_staging. Accessed December 13, 2019.

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