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To: Valued Customer

PRODUCT APPROVAL NOTICE

TABRECTA

Novartis Pharmaceuticals Corporation announces that TABRECTA™ (capmatinib) tablets was approved by the US Food and Drug Administration on May 6, 2020.

Indication
TABRECTA is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Please review the following table for important packaging information:

Salable Units		
NDC Number	0078-0716-56	0078-0709-56
Tablet Strength	200 mg	150 mg
Package Size	56 tablets	56 tablets
Wholesale Price	$8,975.00	$8,975.00

TABRECTA will be available to ship on or about May 11, 2020.

All orders must be placed with a distributor listed below:

Product	Novartis-Designated Distributors
TABRECTA™ (capmatinib) tablets	ASD Healthcare Cardinal Health McKesson Specialty Health

TABRECTA will be available for purchase by any licensed pharmacy.

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TABRECTA is available by prescription only.

Please see Important Safety Information below and full Prescribing Information for TABRECTA:

https://www.novartis.us/sites/www.novartis.us/files/tabrecta.pdf

Additional medical information may be requested from Medical Information by calling toll free: 1-888-NOW-NOVA (1-888-669-6682).

Important Safety Information

Interstitial Lung Disease (ILD)/Pneumonitis. ILD/pneumonitis, which can be fatal, occurred in patients treated with TABRECTA. ILD/pneumonitis occurred in 4.5% of patients treated with TABRECTA in the GEOMETRY mono-1 study, with 1.8% of patients experiencing grade 3 ILD/pneumonitis and 1 patient experiencing death (0.3%). Eight patients (2.4%) discontinued TABRECTA due to ILD/pneumonitis.

Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, fever). Immediately withhold TABRECTA in patients with suspected ILD/pneumonitis and permanently discontinue if no other potential causes of ILD/pneumonitis are identified.

Hepatotoxicity. Hepatotoxicity occurred in patients treated with TABRECTA. Increased alanine aminotransferase (ALT)/aspartate aminotransferase (AST) occurred in 13% of patients treated with TABRECTA in GEOMETRY mono-1. Grade 3 or 4 increased ALT/AST occurred in 6% of patients. Three patients (0.9%) discontinued TABRECTA due to increased ALT/AST.

Monitor liver function tests (including ALT, AST, and total bilirubin) prior to the start of TABRECTA, every 2 weeks during the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop increased transaminases or bilirubin. Based on the severity of the adverse reaction, withhold, reduce dose, or permanently discontinue TABRECTA.

Risk of Photosensitivity. Based on findings from animal studies, there is a potential risk of photosensitivity reactions with TABRECTA. In GEOMETRY mono-1, it was recommended that patients use precautionary measures against ultraviolet exposure, such as use of sunscreen or protective clothing, during treatment with TABRECTA. Advise patients to limit direct ultraviolet exposure during treatment with TABRECTA.

Embryo-Fetal Toxicity. Based on findings from animal studies and its mechanism of action, TABRECTA can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TABRECTA and for 1 week after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with TABRECTA and for 1 week after the last dose.

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Most Common Adverse Reactions. The most common adverse reactions (≥20%) were peripheral edema (52%), nausea (44%), fatigue (32%), vomiting (28%), dyspnea (24%), and decreased appetite (21%). The most common grade 3 adverse reactions (≥2%) were peripheral edema (9%), fatigue (8%), dyspnea (7%), nausea (2.7%), vomiting (2.4%), and noncardiac chest pain (2.1%).

Clinically Relevant Adverse Reactions. Clinically relevant adverse reactions observed in <10% of patients were pruritus (allergic and generalized), ILD/pneumonitis, cellulitis, acute kidney injury (including renal failure), urticaria, and acute pancreatitis.

Laboratory Abnormalities. Select laboratory abnormalities (≥20%) worsening from baseline in patients who received TABRECTA were decreased albumin (68%), increased creatinine (62%), decreased lymphocytes (44%), increased ALT (37%), increased alkaline phosphatase (32%), increased amylase (31%), increased gamma-glutamyltransferase (29%), increased lipase (26%), increased AST (25%), decreased hemoglobin (24%), decreased leukocytes (23%), decreased sodium (23%), decreased phosphate (23%), increased potassium (23%), and decreased glucose (21%).