

Precision Oncology Drug Approvals in 2020 - New Drugs and Expanded Indications

| Approval Date | Drug | Company | New/ Expanded Indication | Indication | Companion Dx₁ | Other Dx₂ |
|----------------------|--|---------------------|---------------------------------|--|---|-----------------------------|
| 1/9/2020 | avapritinib (Ayvakit) | Blueprint Medicines | N | unresectable/metastatic gastrointestinal stromal tumors; PDGFRA exon 18 mutation, including PDGFRA D842V | | Y |
| 2/25/2020 | neratinib (Nerlynx) w/capecitabine | Puma Biotechnology | E | advanced/metastatic breast cancer; after at least two other HER2 targeted therapies; HER2 positive | | Y |
| 4/8/2020 | encorafenib (Braftovi) w/cetuximab (Erbix) | Pfizer | E | metastatic colorectal cancer; BRAF V600E mutation | Qiagen's theascreen BRAF V600E RGQ PCR Kit | |
| 4/17/2020 | tucatinib (Tukysa) w/trastuzumab (Herceptin) plus capecitabine | Seattle Genetics | N | unresectable, metastatic, second-line breast cancer; HER2 positive | | Y |
| 4/17/2020 | pemigatinib (Pemazyre) | Incyte | N | locally advanced/metastatic cholangiocarcinoma; FGFR2 fusion/rearrangement | Roche/Foundation Medicine's FoundationOne CDx | |
| 4/22/2020 | sacituzumab govitecan-hziy (Trodelvy) | Immunomedics | N | third-line metastatic triple-negative breast cancer; HER2/ER/PR negative | | Y |
| 5/6/2020 | capmatinib (Tabrecta) | Novartis | N | metastatic non-small cell lung cancer; MET exon14 skipping mutation | Roche/Foundation Medicine's FoundationOne CDx | |
| 5/8/2020 | selpercatinib (Retevmo) | Eli Lilly | N | metastatic non-small cell lung cancer; advanced medullary thyroid cancer and other advanced thyroid cancers in patients at least 12 years old; RET mutation/fusion | | Y |

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| 5/8/2020 | olaparib (Lynparza) w/bevacizumab (Avastin) | AstraZeneca | E | maintenance for advanced ovarian cancer responsive to first-line, platinum chemo; homologous recombination deficiency-positive (BRCA1/2 mutation or genomic instability) | Myriad Genetics' MyChoice CDx | |
| 5/15/2020 | rucaparib (Rubraca) | Clovis Oncology | E | metastatic castration-resistant prostate cancer previously on androgen receptor-directed therapy and taxane-based chemotherapy; BRCA1/2 mutated | Roche/FoundationOne Liquid CDx | |
| 5/15/2020 | nivolumab (Opdivo) plus ipilimumab (Yervoy) | Bristol Myers Squibb | E | first-line metastatic non-small cell lung cancer; PD-L1 expression in at least 1 percent tumor cells; no EGFR/ALK alterations | Agilent Technologies' PD-L1 IHC 28-8 pharmDx | |
| 5/18/2020 | atezolizumab (Tecentriq) | Genentech | E | first-line metastatic non-small cell lung cancer; PD-L1 expression in at least 50 percent of tumor cells or 10 percent of tumor infiltrating immune cells; no EGFR/ALK alterations | Roche's Ventana PD-L1 (SP142) Assay | |
| 5/19/2020 | olaparib (Lynparza) | AstraZeneca | E | metastatic castration-resistant prostate cancer progressed on enzalutamide or abiraterone; homologous recombination repair gene mutation | Roche/Foundation Medicine's FoundationOne CDx; FoundationOne Liquid CDx; Myriad Genetics' BRACAnalysis CDx | |
| 5/22/2020 | brigatinib (Alunbrig) | Takeda Pharmaceutical | E | metastatic non-small cell lung cancer; ALK positive | Abbott Molecular's Vysis ALK Break Apart FISH Probe Kit | |
| 5/29/2020 | ramucirumab (Cyramza) w/erlotinib (Tarceva) | Eli Lilly | E | first-line metastatic non-small cell lung cancer; EGFR exon 19 deletions/exon 21 (L858R) mutations | | Y |

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| 6/16/2020 | gemtuzumab ozogamicin (Mylotarg) | Pfizer | E | newly diagnosed patients at least one- month old who have CD33-positive acute myeloid leukemia | | Y |
| 6/16/2020 | pembrolizumab (Keytruda) | Merck | E | adult and pediatric patients w/ unresectable/metastatic solid tumors progressed on other treatments and out of options; tumor mutational burden high (at least 10 mutations per megabase) | Roche/Foundation Medicine's FoundationOne CDx | |
| 6/18/2020 | tazemetostat (Tazverik) | Epizyme | E | adults w/ relapsed/refractory follicular lymphoma; EZH2 mutation | Roche's cobas EZH2 Mutation Test | |
| 6/29/2020 | pertuzumab/ trastuzumab/ hyaluronidase-zzxf (Phesgo) | Genentech | N | metastatic breast cancer; HER2 positive | | Y |
| 6/29/2020 | pembrolizumab (Keytruda) | Merck | E | first-line metastatic colorectal cancer; MSI- H/ dMMR | | Y |
| 7/24/2010 | brexucabtagene autoleucel (Tecartus) | Gilead/Kite Pharma | N | CAR T-cell therapy for refractory mantle cell lymphoma | | |
| 7/30/2020 | atezolizumab (Tecentriq) w/cobimetinib (Cotellic) plus vemurafenib (Zelboraf) | Genentech | E | advanced melanoma; BRAF V600 mutation | Roche's cobas 4800 BRAF V600 Mutation Test | |
| 9/4/2020 | pralsetinib (Gavreto) | Blueprint Medicines/ Genentech | N | metastatic non-small cell lung cancer; RET fusion | Thermo Fisher Scientific's Oncomine Dx Target Test | |
| 11/13/2020 | pembrolizumab (Keytruda) | Merck | E | locally recurrent, unresectable, metastatic triple- negative breast cancer; PD-L1 expression combined positive score of at least 10 | Agilent Technologies' PD-L1 IHC 22C3 pharmDx | |
| 12/1/2020 | pralsetinib (Gavreto) | Blueprint Medicines/ Genentech | E | advanced/metastatic medullary thyroid cancer, RET mutation; advanced/metastatic thyroid cancer, RET fusion | | Y |

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| 12/16/2020 | margetuximab (Margenza) | MacroGenics | N | metastatic breast cancer; two prior HER2-targeted treatments; HER2-positive | | Y |
| 12/18/2020 | osimertinib (Tagrisso) | AstraZeneca | E | adjuvant non-small cell lung cancer; EGFR mutations | Roche's cobas EGFR Mutation Test | |

N - New drug; E - Expanded indication

1 FDA cleared/approved test alongside drug approval

2 Other FDA and non-FDA approved tests available for identifying the patient population that can receive treatment

This list highlights precision oncology drugs the FDA approved in 2020 that rely on biomarker testing to determine who should receive them or are n-of-one treatments (i.e. autologous CAR T-cell therapies). This list does not include drugs that the FDA considers personalized based on other criteria.