Overview of 2018 CDER Drug Approvals in Hematology/Oncology

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2018 OHOP New Drug Approvals

- New Molecular Entities (NMEs): 15
  - Solid tumors: 8
  - Hematologic malignancies: 7
- Supplements: 30
  - Solid tumors: 22
  - Hematologic malignancies: 8
- Biosimilars: 2
  - Biosimilar to Epogen/Procrit
  - Biosimilar to Neulasta
- Accelerated Approval: 6

Talazoparib (Talzenna®)

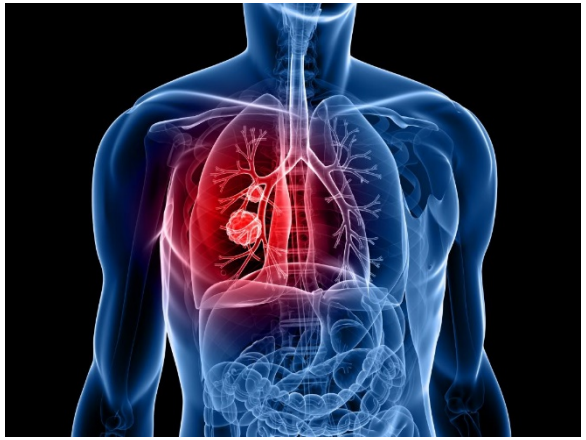
- Indication: For patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm), HER2-negative locally advanced or metastatic breast cancer
- Patients selected for Talzenna treatment based on a companion diagnostic test
- Dosing: 1 mg tab orally once a day

Talazoparib (Talzenna®)

- Regular approval based on EMBRACA Trial
- Randomized (2:1) trial in 431 patients with gBRCAm HER2- locally advanced or metastatic breast cancer comparing Talzenna 1 mg to an active control of physician's choice of chemotherapy
- Primary endpoint was Progression Free Survival (PFS)
- Results (PFS):
  - Talazoparib arm: 8.6 months
  - Chemotherapy Arm: 5.6 months
  - (HR 0.54; 95% CI: 0.41, 0.71; $p<0.0001$)

Dacomitinib (Vizimpro®)

- Indication: First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test
- Dosing: 45 mg tab orally once daily

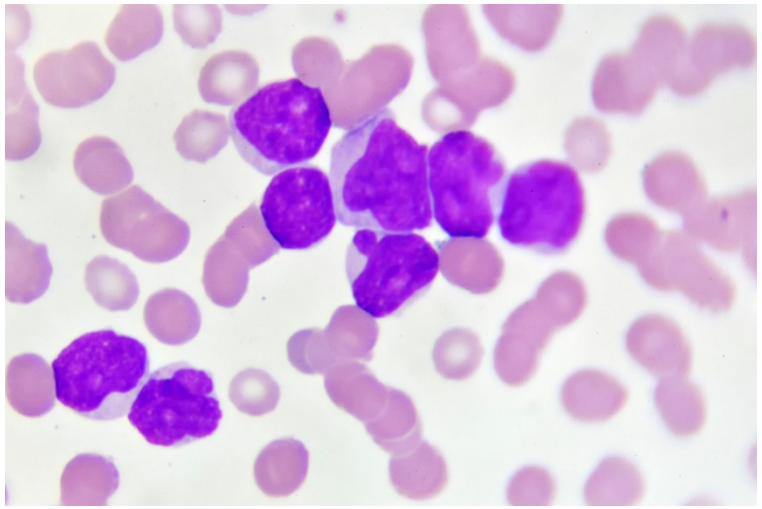


Dacomitinib (Vizimpro®)

- Regular approval based on ARCHER 1050
- Population:
  - Unresectable, metastatic NSCLC with no prior therapy (or recurrent disease with a minimum of 12 months disease-free)
  - EGFR exon 19 deletion or Exon 21 L858R substitution mutations
- 452 patients were randomized 1:1 to receive either Vizimpro 45 mg orally once daily or Iressa 250 mg orally once daily
- Results (PFS):
  - Vizimpro arm: 14.7 months
  - Gefitinib arm: 9.2 months
  - (HR 0.59; 95% CI: 0.47, 0.74; $p<0.0001$)

Ivosidenib (Tibsovo®)

- Indication: Adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test
- Dosing: 500 mg orally once daily



Ivosidenib (Tibsovo®)

- Regular approval based on Study AG-120-C-001
- Single-arm, multicenter trial of 174 patients
- Population: Relapsed or refractory AML with an IDH1 mutation
- Efficacy based on response rate:
  - CR+CRh*: 32.8% (95% CI: 25.8%-40.3%)
  - Median response duration: 8.2 months (95% CI: 5.6-12 months)
  - 37.4% of patients who were transfusion dependent at baseline became transfusion independent

*CR: Complete remission
CRh: Complete remission with partial hematologic recovery

More Information

https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm