**Supplementary Table S1. Review of 2019 FDA Oncology Drug Approvals based on randomized phase 3 clinical trials.** Published manuscripts supporting 23 of the 26 approvals were retrieved (as of March 2020) and the eligibility criteria specifics for each trial were extracted from each manuscript.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study | Disease setting | Hemoglobin (g/dl) | Absolute neutrophil count (x 109/L) | Platelets (x 109/L) | Total Bilirubin | AST/ALT | Cr/CrCl (mL/min) | Frequency | Reference |
| POLO: olaparib maintenance versus placebo | BRCA mutated metastatic pancreatic cancer | ≥ 9 | ≥ 1.5 | ≥ 100 | < 1.5 x ULN | ≤ 2.5 x ULN; ≤ 5X with liver mets | ≤ 1.5 x ULN | every 28 days | Golan et al. NEJM 2019;381:317-327 |
| ARCHES: androgen deprivation therapy + enzaluatmide/placebo | metastatic hormone sensitive prostate cancer | ≥ 10 | ≥ 1.5 | ≥ 100 | < 1.5 x ULN unless Gilbert's | < 2.5 x ULN | ≤ 2 mg/dl | D1, D29, then every 12 weeks | Armstrong et al. JCO 2019;37: 2974-2986. |
| IMPOWER 130: carboplatin/nab-paclitaxel ± atezolizumab | first line non-squamous NSCLC | ≥ 9 | ≥ 1.5 | ≥ 100 | ≤ 1.25 x ULN unless Gilbert's (3X) | ≤ 2.5 x ULN; ≤ 5X with liver mets | ≤ 1.5 x ULN | weekly CBC; Q21D chemistry | West et al. Lancet Oncol 2019;20:924-937 |
| ELEVATE TN: acalabrutinib | CLL/SLL | NA | NA | NA | NA | NA | NA | NA | Not published |
| ASCEND: acalabrutinib | CLL/SLL | NA | NA | NA | NA | NA | NA | NA | Not published |
| CASSIOPEIA: bortezomib, thalidomide, dexamethasone ± daratumumab | newly diagnosed MM pre and post transplant | ≥ 7.5 | ≥ 1 | ≥ 70 | < 1.5 x ULN | < 2.5 x ULN | ≥ 40 ml/min | NA | Moreau et al. Lancet 2019;394:29-38 |
| TITAN: androgen deprivation therapy + apalutamide/placebo | metastatic castration sensitive prostate cancer | ≥ 9 | ≥ 1.5 | ≥ 100 | < 1.5 x ULN unless Gilbert's | < 2.5 x ULN | ≤ 2 x ULN | every cycle x 12 then every 2 cycles (cycle = 28 days) | Chi et al. NEJM 2019;381:13-24 |
| KEYNOTE 181: pembrolizumab | esophageal | NA | NA | NA | NA | NA | NA | NA | Not published |
| ARAMIS: androgen deprivation therapy + darolutamide/placebo | nonmetastatic castration resistant prostate cancer | ≥ 9 | ≥ 1.5 | ≥ 100 | < 1.5 x ULN unless Gilbert's | < 2.5 x ULN | ≤ 2 x ULN | D1, D15, D29 then every 16 weeks | Fizazi et al. NEJM 2019;380:1235-1246 |
| MAIA: lenalidomide/dexamethasone ±daratumumab | transplant ineligible newly diagnosed MM | ≥ 7.5 | ≥ 1 | ≥ 70 | < 1.5 x ULN unless Gilbert's | < 2.5 x ULN | ≥ 30 ml/min/1.73mm2 | CBC weekly x 2 cycles; Q2 wks x 3 cycles; then Qcycle (28days); chemistry Q 28dcycle | Facon et al. NEJM 2019;380:2104-2115. |
| KEYNOTE 48: pembrolizumab vs pembro + chemotherapy vs cetuximab + chemo | untreated metastatic HNSCC | ≥ 9 | ≥ 1.5 | ≥ 100 | < 1.5 x ULN | ≤ 2.5 x ULN; ≤ 5X with liver mets | ≤ 1.5 x ULN or ≥ 60 ml/min | every cycle (3 weeks) | Burthness et al. Lancet 2019;394:1915-1928 |
| AUGMENT: rituximab + lenalidomide/placebo | relapsed/refractory indolent lymphoma | ≥ 8 | ≥ 1.5 | ≥ 75 | ≤ 2 mg/dl unless liver disease | ≤ 3 x ULN unless liver disease | ≥ 30 ml/min | weekly cycle 1; every 2 weeks cycles 2-4; every cycle | Leonard et al. JCO 2019;37:1188-1199. |
| SOLAR1: fulvestrant + alpelisib/placebo | HR+, HER2 - breast cancer | ≥ 9 | ≥ 1.5 | ≥ 100 | WNL unless Gilbert's | ≤ 2.5 x ULN; ≤ 5X with liver mets | ≥ 35 ml/min | CBC every 2 weeks for cycles 1 and 2, then every cycle; chemistry every cycle (28 days) | Fabrice et al. NEJM 2019;380:1929-1940 |
| CLL 14: venetoclax/obinutuzumab vs chlorambucil/obinutuzumab | previously untreated CLL | NA | ≥ 1 | ≥ 30 | ≤ 2 x ULN unless liver disease | ≤ 2 x ULN unless dz | ≥ 30 ml/min | weekly cycle 1; every 2 weeks cycles 2-12 | Fischer et al NEJM 2019;380:2225-2236 |
| Javelin Renal 101: avelumab + axitinib versus sunitinib | advanced untreated RCC | ≥ 9 | ≥ 1.5 | ≥ 100 | < 1.5 x ULN | < 2.5 x ULN | ≥ 50 ml/min | Q2 week CBC and core chemistry | Motzer at al. NEJM 2019;380:1103-1115 |
| REACH-2: ramucirumab vs placebo | HCC post sorafenib | ≥ 9 | ≥ 1 | ≥ 75 | < 1.5 x ULN | < 5 x ULN | ≥60 ml/min | CBC and chemistry every 2 weeks | Zhu et al. Lancet Oncol 2019;20:282-296. |
| KATHERINE: TDM1 vs trastuzumab | HER2+ breast with residual invasive disease post neoadjuvant therapy | ≥ 9 | ≥ 1.2 | ≥ 100 | WNL except Gilbert's | ≤ 1.5 x ULN | ≤ 1.5 x ULN | CBC and chemistry every cycle (21 days) | von Minckwitz et al. NEJM 2019;380:617-628. |
| KEYNOTE 426: pembrolizumab plus axitinib vs sunitinib | untreated advanced RCC | ≥ 9 | ≥ 1.5 | ≥ 100 | ≤ 1.5 x ULN | < 2.5 x ULN | ≤ 1.5 x ULN or ≥ 40 ml/min | CBC and chemistry every 21 days x 7 cycles then every 42 days | Rini et al. NEJM 2019;380:1116-1127 |
| KEYNOTE 042: pembrolizumab vs platinum based chemo | untreated NSCLC | ≥ 9 | ≥ 1.5 | ≥ 100 | WNL | ≤ 2.5 x ULN; ≤ 5X with liver mets | ≤ 1.5 x ULN or ≥ 50ml/min | CBC and chemistry every cycle (21 days) up to cycle 10 then every other cycle | Mok et al. Lancet 2019;393:1819 - 1830 |
| IMPOWER 133: carboplatin/etoposide + atezolizumab/placebo | untreated extensive SCLC | ≥ 9 | ≥ 1.5 | ≥ 100 | ≤ 1.25 x ULN unless Gilbert's (3X) | ≤ 2.5 x ULN; ≤ 5X with liver mets | ≤ 1.5 x ULN | CBC and chemistry every 21 days | Horn et al. NEJM 2018;379:2220-2229 |
| IMPASSION 130: nab-paclitaxel + atezolizumab/placebo | untreated metastatic TNBC | ≥ 9 | ≥ 1.5 | ≥ 100 | ≤ 1.25 x ULN unless Gilbert's (3X) | ≤ 2.5 x ULN; ≤ 5X with liver mets | ≥ 30 ml/min | weekly CBC and chemistry | Schmid et al. NEJM 2018;379:2108-2121 |
| HannaH: neoadjuvant IV vs subcutaneous trastuzumab + chemotherapy | HER2+ early breast cancer | ≥ 10 | ≥ 1.5 | ≥ 100 | ≤ 1.25 x ULN | ≤ 2.5 x ULN | ≤ 1.5 x ULN | CBC and chemistry every 21 days | Jackisch et al. JAMA Oncology 2019;5 (5)e190339. |
| TAGS: trifluridine/tipiracil vs placebo | gastric/GEJ cancer with at least 2 prior regimens | ≥ 9 | ≥ 1.5 | ≥ 100 | ≤ 1.5 x ULN | ≤ 3 x ULN; ≤ 5X with liver mets | ≤ 1.5 mg/dl | CBC/chemistry D15 cycle 1 then every 28 days (cycle) | Shitara et al. Lancet Oncol 2018;19:1437-1448 |
| Keynote 054/EORTC 1325: adjuvant pemrbolizumab vs placebo | resected stage 3 melanoma | ≥ 9 | ≥ 1.5 | ≥ 100 | ≤ 1.5 x ULN | ≤ 2.5 x ULN | ≤ 1.5 x ULN or ≥ 60ml/min | CBC and chemistry every 6 weeks | Eggermont et al. NEJM 2018;378:1789-1801 |
| Celestial: Cabozamtinib vs placebo | HCC post sorafenib | ≥ 8 | ≥ 1.2 | ≥ 60 | ≤ 2 mg/dl | < 5X ULN | ≤ 1.5 x ULN or ≥ 40ml/min | CBC and chemistry every 2 weeks x 9 weeks then every 4 weeks | Abou-Alfa et al. NEJM 2018;379:54-63**.** |