ESMO DATA REVIEW 2025
December 4, 2025

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Breast Cancer

DESTINY-Breast11: Neoadjuvant T-DXd→THP achieved a 67.3% pCR rate (vs 56.3% with ddAC→THP), improving response and may become a standard of care in the curative intent setting for HER2+ early breast cancer – not yet approved

DESTINY-Breast05: Post-neoadjuvant T-DXd was associated with improvements in invasive disease-free survival vs T-DM1 at 3-yr 92.4% vs 83.7% (HR: 0.47; P <.0001) and may become a standard of care in the curative intent setting for HER2+ early breast cancer – not yet approved

DESTINY-Breast09: In first-line HER2+ metastatic breast cancer, T-DXd plus pertuzumab significantly improved PFS (median ~ 40.7 months vs 26.9 months; HR 0.56) versus THP irrespective of PI3Km or HR status– not yet approved, PDUFA date of Jan 23, 2026

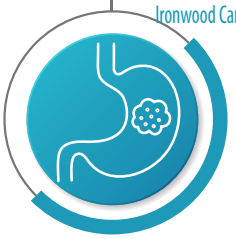
ASCENT-03: In first-line metastatic TNBC patients ineligible for PD-1/PD-L1 inhibitors, sacituzumab govitecan reduced the risk of progression or death by 38% vs standard chemotherapy (median PFS 9.7 vs 6.9 months; HR 0.62) – not yet approved

TROPION-Breast02: In first-line metastatic TNBC patients ineligible for PD-1/PD-L1 inhibitors, datopotamab deruxtecan improved OS (23.7 vs 18.7 mo, HR: 0.79) and PFS (10.8 vs 5.6 mo, HR: 0.57) by ~5 months versus chemotherapy – not yet approved

evERA BC: In ER+/HER2– advanced breast cancer post-CDK4/6 inhibitors, giredestrant + everolimus reduced the risk of progression by ~44% in the overall population and ~62% in ESR1-mutant patients versus standard endocrine therapy + everolimus – not yet approved

VIKTORIA-1: Gedatolisib plus fulvestrant ± palbociclib improved PFS in PIK3CA wild-type, HR+/HER2– advanced breast cancer post-CDK4/6 inhibitors (triplet HR 0.24, doublet HR 0.33 vs fulvestrant) – not yet approved

GU/GI Cancer



KEYNOTE-905: Perioperative enfortumab vedotin + pembrolizumab significantly improved EFS and OS vs cystectomy alone, with high pCR rates and should be a new perioperative standard of care option for cisplatin-ineligible muscle-invasive bladder cancer – now approved!

IMvigor011: In ctDNA-positive patients, adjuvant atezolizumab improved DFS and OS vs placebo, establishing ctDNA-guided MRD selection as a powerful tool to identify who benefits from adjuvant immunotherapy – not yet approved

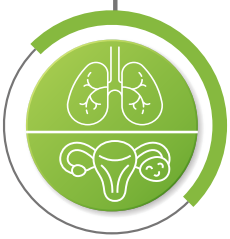
PSMAddition: In first-line high-risk localized prostate cancer, adding dding enzalutamide to ADT + radiotherapy modestly improved PSA-PFS, but the overall benefit–risk profile was mixed – not yet approved

FORTITUDE-101: In first-line FGFR2b-overexpressing gastric/GEJ cancer, Bemarituzumab + chemotherapy demonstrated encouraging OS and PFS trends vs chemotherapy alone, supporting FGFR2b-targeting as a promising first-line strategy, confirmatory evidence still required – not yet approved

AGITG DYNAMIC-III: For patients with ctDNA- negative stage III colon cancer, ctDNA-guided de-escalation was feasible and reduced chemotherapy exposure by 53.8%, but non-inferiority for 3-yr RFS was not met (3-yr RFS 85.3% vs 88.1%) – not yet approved

RC48-C016: In first-line HER2-expressing locally advanced or metastatic urotherlial carcinoma, disitamab vedotin + toripalimab produced high ORR in HER2-overexpressing tumors (≈80%) and promising PFS signals in HER2-low tumors when combined with chemo – not yet approved

Lung & Ovarian Cancers



HARMONI-6: In first-line advanced squamous NSCLC, Ivonescimab + platinum-taxane improved mPFS 11.14 (vs 6.90 months with tislelizumab) and may become a standard of care in the curative intent setting for advanced squamous NSCLC – not yet approved

FLAURA2: In first-line EGFRm advanced NSCLC, osimertinib plus platinum-pemetrexed achieved a median OS of 47.5 months (vs 37.6 months with osimertinib monotherapy) and consistent benefits across key subgroups (CNS, mutation type, TP53 status) – FDA approved Feb 16, 2024

OptiTROP-Lung04: In EGFRm NSCLC following post-EGFR-TKIs, sac-TMT improved PFS (8.3 vs 4.3 months, HR 0.49; P<0.0001) and ORR (60.6% vs 43.1%) versus chemotherapy – not yet approved

ALEX: In first-line ALK-positive advanced NSCLC, alectinib achieved durable overall-survival and long-term CNS control versus crizotinib, reinforcing alectinib's long-standing role as first-line standard of care for ALK-positive advanced NSCLC – FDA approved Nov 6, 2017

ENGOT-ov65/KEYNOTE-B96: In platinum-resistant recurrent ovarian cancer with up to 2 prior lines of therapy, pembrolizumab plus weekly paclitaxel, with or without bevacizumab demonstrated overall-survival benefit versus placebo – not yet approved

REJOICE-Ovarian01: In pretreated, platinum-resistant high-grade ovarian cancer, R-DXd achieved confirmed ORR (~50–51% across tested doses) and the 5.6 mg/kg dose was favored for risk/benefit – FDA Breakthrough Therapy Sept 2025, not yet approved

cornerstone specialty network™

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