

## October 24, 2024



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**ESMO DESTINY-Breast12**: Trastuzumab deruxtecan showed clinically, meaningful activity for HER2+ mBC regardless of brain mets 2024: **KEYNOTE-522**: Adding neoadjuvant/adjuvant pembrolizumab with neoadjuvant chemotherapy improves median survival in patients with high-risk, early-stage TNBC **Breast CAPItello-290**: Capivasertib does *not* improve survival in patients with metastatic TNBC, regardless of Cancer presence or absence of PIK3CA/AKT1/PTEN-alterations **Cervical ENGOT-cx11/GOG-3047/KEYNOTE-A18**: Adding pembrolizumab to concurrent CRT improves median Cancer survival patients with newly diagnosed, previously untreated, high-risk locally advanced cervical cancer **NATALEE**: The approval of ribociclib (Sept 17, 2024) with an aromatase inhibitor in the adjuvant setting Key provides expanded treatment options (which had included only amebaciclib for node+) for patients with HR+ HER2- stage II (node neg or +) and III early breast cancer at high risk of recurrence, based on IDFS **Takeaways DESTINY-Breast06**: Regardless of sample location/type, HR+, HER2-low or HER2-ultralow status, trastuzumab deruxtecan demonstrates a benefit for patients following endocrine therapy. Notable discordance between local and central testing for HER2 low and zero. **A&C** FDA priority review granted Oct 1, 2024; PDUFA date Feb 1, 2025 **ICARUS-Breast01**: HER3-DXd leads to fairly high response rate (>50%) in patients with HR+/HER2-negative @EdithPerezMD advanced breast cancer after prior CDK4/6i; biomarker analysis may (or may not) be predictive **INAVO120:** FDA approval of involisib+palbociclib+fulvestrant as rest-line Rx for mBC in pts whose tumors

have PI3K alterations based on the FoundationOne liquid Cdx assay

ESMO 2024: GU / GI Cancer **POD1UM-303/InterAACT 2:** Retifanlimab plus carboplatin and paclitaxel provides benefit over the current standard of care chemotherapy and should be considered as a new standard of care for patients with locally recurrent or metastatic squamous cell carcinoma of the anal canal – not yet approved

**LEAP-012**: Pembrolizumab plus lenvatinib in combination with TACE has the potential to benefit patients with unresectable, non-metastatic hepatocellular carcinoma and may provide a new treatment option

Key Takeaways

**EORTC-GUCG 1333/PEACE-3**: The addition of Ra223 to enzalutamide significantly benefits patient with metastatic castration-resistant prostate cancer and this combination should be considered as a new standard of care – not yet approved

**NIAGARA**: Durvalumab is the first immunotherapy regimen given in combination with chemotherapy before and as a monotherapy after surgery to provide benefit for patients with muscle-invasive bladder cancer and should be considered a new standard of care – not yet approved

Q&A @SujithKalmadi MD cornerstone specialty network

**TiNivo-2**: Tivozanib as a monotherapy at the recommended dose of 1.34 mg should be considered as a second-line treatment option in patients following progression on previous ICI therapy. No benefit to patients with ICI rechallenge

ESMO 2024:	<b>ADRIATIC:</b> Durvalumab consolidation therapy should be considered a new standard of care option for patients with LS- SCLC regardless of prior exposure to prophylactic cranial irradiation (PCI) or concurrent chemoradiotherapy (CRT) components. <i>PDUFA date: fourth quarter of 2024</i>
Lung Cancer	<b>CCTG BR.31:</b> Adjuvant durvalumab does not benefit patients with EGFR- or ALK- NSCLC when given after complete resection with or without optional chemotherapy, regardless of PD-L1 status
Kev	<b>RELATIVITY-104:</b> Nivolumab plus relatlimab plus platinum doublet chemotherapy provides benefit to patients with metastatic NSCLC <i>Approved for the treatment of advanced melanoma</i>
Key Takeaways	On August 19, 2024, the FDA approved lazertinib (Lazcluze, Janssen Biotech, Inc.) in combination with amivantamab- vmjw (Rybrevant, Janssen Biotech, Inc.) for the first-line treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test.
<u> </u>	On September 19, 2024, the FDA approved amivantamab-vmjw (Rybrevant, Janssen Biotech, Inc.) with carboplatin and pemetrexed for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor.
<b>Q&amp;A</b> @EricSchaeferMD	On September 25, 2024, the FDA approved osimertinib (Tagrisso, AstraZeneca Pharmaceuticals) for adult patients with locally advanced, unresectable (stage III) non-small cell lung cancer (NSCLC) whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
specialty network	On October 3, 2024, the FDA approved nivolumab (Opdivo, Bristol Myers Squibb Company) with platinum-doublet chemotherapy as neoadjuvant treatment, followed by single-agent nivolumab after surgery as adjuvant treatment, for adults with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.