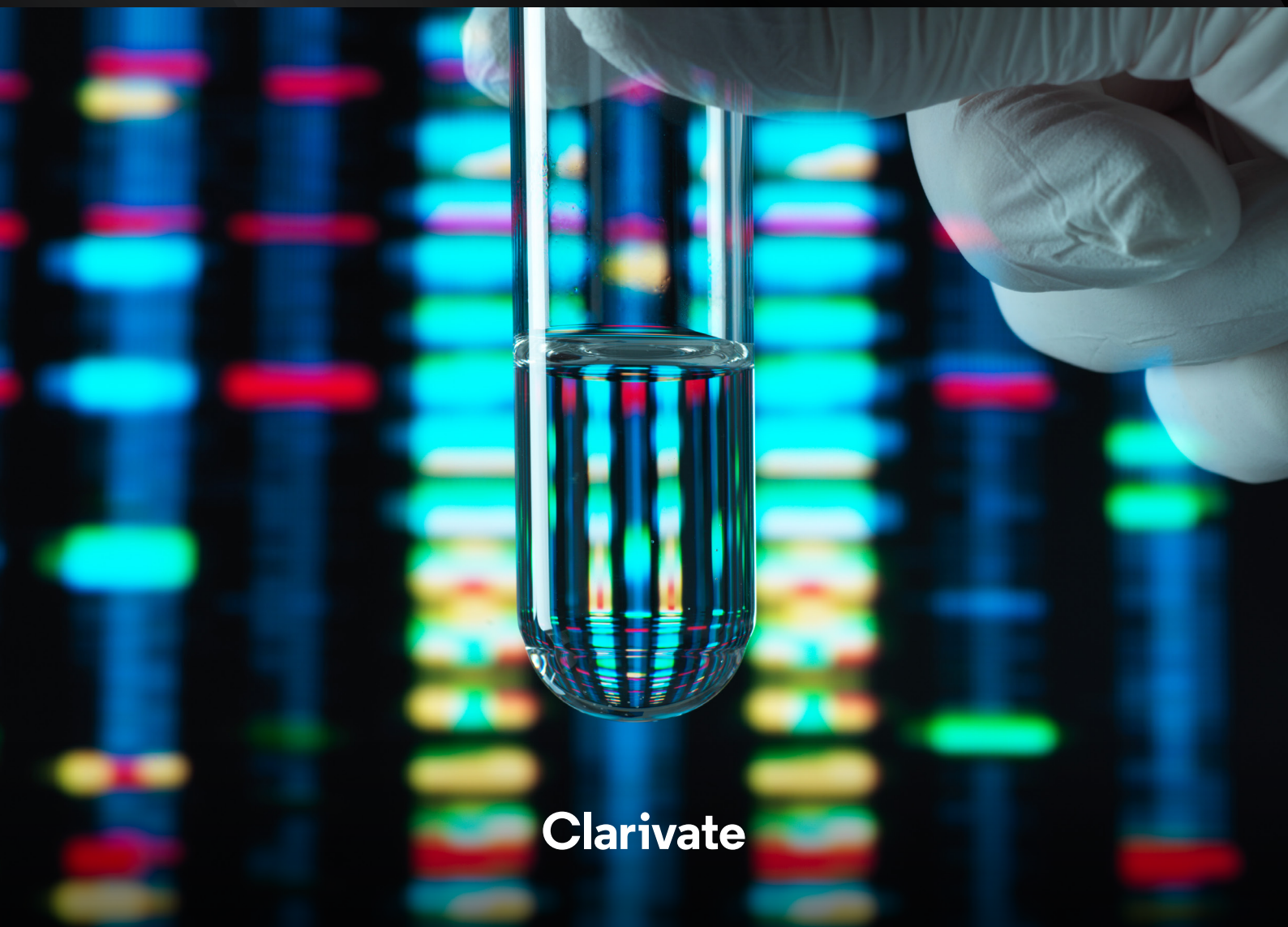
Oncology Drugs to Watch

Top takeaways from ASCO 2025



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Introduction

Science opens up new fronts against cancer

The ASCO 2025 Annual Meeting in Chicago was overshadowed by events in Washington, D.C. — tariffs, funding cuts, tensions with Mainland China and the threat of 'Most favored nation' price indexing for prescription drugs among them. But beyond the distant political wrangling, it was a year of striking breakthroughs in the war on cancer as bets on emerging modalities like bispecific antibodies, T-cell engagers, antibody drug conjugates, radioligand therapeutics and gene editing platforms began to pay off.

The theme for this year's conference, 'Driving knowledge to action: building a better future,' struck an optimistic note. The future is uncertain, but science is delivering patients cause for hope.

Clarivate oncology analysts pored over hundreds of ASCO presentations to identify 13 of particular interest globally, along with an additional four of significance to the burgeoning Mainland China marketplace. These studies covered therapeutics for small- and non-small cell lung cancer, gastric cancer, head and neck cancer, melanomas, prostate cancer, breast cancer, ovarian cancer, colorectal cancer and more.

"ASCO 2025 has demonstrated that Immunotherapies continue to redefine cancer care and the potential benefit of placing these earlier in the treatment paradigm. Novel mechanisms of action like ADCs and BiTEs are breaking the ceiling in difficult to treat cancers."

Leena Kathuria,
Senior Manager, Healthcare Research and Data Analytics.

Methodology

How we identified the key abstracts and trends at the 2025 ASCO Annual Meeting

As part of our Drugs to Watch program, Clarivate oncology experts sifted through more than 6,000 abstracts presented or published at the 2025 ASCO Annual Meeting, analyzing the data and performing a qualitative assessment to shortlist those releases expected to have a significant impact on the cancer treatment landscape and/or the drug development pipeline. In addition, Clarivate Asia-Pacific oncology experts identified key highlights for results presented from Mainland China. This report provides an in-depth analysis of groundbreaking or notable clinical trial data releases across oncology indications.

We shortlisted these abstracts based on, but not limited to, the following criteria:

- Unprecedented efficacy benefit over current therapies
- Clinical trials addressing unmet need in an underserved patient population
- Impact on competitive landscape and market dynamics
- Impact on the oncology drug pipeline
- Novel drug class or combinatorial approach

Contributors

Anna Duran
Analyst, Oncology

Antonio Camera
Analyst, Oncology

Boya Zhang
Analyst, China In-Depth

Carmo Castilho Soares
Analyst, Oncology

Catherine Willoughby
Analyst, Oncology

Charlotte Jago
Senior Analyst, Oncology

Esther Coronado
Analyst, Oncology

Glenda Walker
Senior Analyst, Oncology

Joan Tur
Senior Analyst, Oncology

Julia Morris
Analyst, Oncology

Karan Verma
Associate Principal Analyst, China In-Depth

Khurram Nawaz
Senior Manager, Oncology

Laura Ramos
Analyst, Oncology

Leena Kathuria
Senior Manager, Oncology

Louis Perdios
Manager, Oncology

Pragati Tripathi
Analyst, Oncology

Preeti Attri
Senior Analyst, Oncology

Rachel Webster
Director, Oncology & Biosimilars

Ruchita Kumar,
Senior Manager, China In-Depth

Sahil Arora
Analyst, China In-Depth

Sarvendu Kumar
Manager, Oncology

Vandana
Analyst, Oncology

Stay on top of the fast-moving oncology landscape and make data-driven decisions

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Disease Landscape & Forecast provides comprehensive market intelligence on current and emerging therapies, addressable population size and the market outlook across 85+ indications to help identify opportunities and optimize long-term disease strategy. Epidemiology Intelligence provides insight to size the market and understand patient populations with a combination of incidence and prevalence literature review across 1200+ diseases and procedures. In-depth disease specific forecasts and U.S. claim-based insights are available for 220+ indications.

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Cortellis Clinical Trials Intelligence is a comprehensive source of detailed insights on clinical sites and trial protocols including biomarkers, targets and indications to optimize clinical trial planning.

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Web of Science is the world's largest publisher-neutral citation index and research intelligence platform. It organizes the world's research information to enable academia, corporations, publishers and governments to accelerate the pace of research.

Derwent Innovation is a market leading patent research and analytics platform delivering access to globally trusted patents and scientific literature. Enhanced content, proprietary search and data intelligence technology helps a global community of more than 40,000 innovators and legal professionals find answers to complex questions.

Key ASCO 2025 takeaways

1. OPDIVO significantly improves survival in resectable NSCLC[1-3]

Updated clinical data further strengthens Opdivo's position in resectable NSCLC.

The treatment of choice for early-stage NSCLC is curative-intent resection with the optional addition of [neo]adjuvant chemotherapy or, following the entry of several immunotherapy agents into this setting, [neo]adjuvant chemoimmunotherapy. Opdivo is the only immunotherapy approved in a neoadjuvant-alone regimen, based on the Phase 3 CheckMate-816 trial which showed median event-free survival (EFS) of 43.8 vs. 18.4 months (HR 0.66) with Overall Survival (OS) reported to be significant and clinically meaningful[4]. Detailed final OS data were revealed at ASCO 2025. Opdivo is also approved for perioperative use, based on CheckMate-77T which showed median EFS of 40.1 vs. 17.0 months (HR 0.59). Updated EFS and first interim OS data from this trial were revealed at ASCO 2025.

Key ASCO findings

At the final OS analysis of CheckMate-816 of neoadjuvant Opdivo plus chemotherapy vs. neoadjuvant chemotherapy, median OS was not reached vs. 73.7 months (HR 0.72, P = 0.0479), with 5-year OS rates of 65% vs. 55%. The OS HR was 0.11 for nivolumab recipients with vs. without pathological complete response (pCR), with 5-year OS rates of 95% vs. 56% respectively.[1-2]

At the first interim OS analysis of CheckMate-77T of perioperative Opdivo plus adjuvant chemotherapy vs. adjuvant chemotherapy, median OS was not reached for both arms (HR 0.85, non-significant), with 2.5-year OS rates of 78% vs. 72% respectively. Median EFS continued to show benefit for perioperative nivolumab (HR 0.61) with 2.5-year EFS rates of 61% vs. 43%.[3]

Market impact

The number of immunotherapies in the resectable NSCLC setting has expanded dramatically since their first entry into this space in 2021, and this range of options, plus unsettled treatment paradigms, makes the space highly dynamic and competitive. Opdivo is the only neoadjuvant-alone immunotherapy option. Clarivate expects that the positive final OS data from CheckMate-816 will strengthen this regimen's place in the market. Although there is the potential for the OS data from the perioperative CheckMate-77T trial to reach significance when mature, and thus to bolster Opdivo's position in the resectable setting, direct competitor Keytruda has already demonstrated significant OS benefits as a perioperative regimen[5]. As treatment dynamics become further complicated with anticipated new regimens join those already available, the demonstration of OS benefit could be a key differentiator.

2. Neoadjuvant TAGRISSO improves major pathological response in early-stage EGFR-mutated NSCLC[6-9]

NeoADAURA is the first Phase 3 trial to demonstrate a benefit for the neoadjuvant use of an EGFR inhibitor (with or without chemotherapy) in patients with resectable EGFR-mutated NSCLC.

AstraZeneca's EGFR inhibitor Tagrisso is approved in the adjuvant, locally advanced, and metastatic settings for certain EGFR-mutated non-small-cell lung cancer (NSCLC) patients. In February 2025, AstraZeneca revealed that the global Phase 3 NeoADAURA trial exploring neoadjuvant Tagrisso with or without chemotherapy for resectable EGFR-mutated stage II-IIIB non-squamous NSCLC met its primary endpoint of major pathologic response (MPR).[7] An improvement in pCR and a trend towards improved EFS over chemotherapy were also reported. These data were presented for the first time at ASCO 2025[6] and published simultaneously in the Journal of Clinical Oncology.[8]

Key ASCO findings

The MPR rate was significantly higher for Tagrisso plus chemotherapy and for Tagrisso alone, each compared with neoadjuvant chemotherapy (26% vs. 25% vs. 2%, both $P < 0.0001$). A similar trend was observed for pCR (4% vs. 9% vs. 0%). Preliminary analyses revealed positive trend towards EFS benefit for Tagrisso plus chemotherapy vs. chemotherapy (HR 0.50, $P = 0.0382$), and for Tagrisso alone vs. chemotherapy (HR 0.73). Furthermore, over 50% of Tagrisso-treated patients with baseline N2 disease were downstaged at surgery vs. 21% of those treated with chemotherapy alone. The safety profile of Tagrisso with or without chemotherapy in NeoADAURA was largely consistent with previous data.

Market impact

Tagrisso could become the first genomic alteration-targeted agent to enter the neoadjuvant setting for resectable NSCLC, offering upfront treatment as an alternative (or possibly in addition) to adjuvant Tagrisso (approved based on the Phase 3 ADAURA trial[9]). Neoadjuvant Tagrisso may be limited to higher-risk N2 patients, and whether the option to use Tagrisso perioperatively offers additional benefit remains to be studied. Clarivate expects AstraZeneca to seek and receive regulatory approval for the neoadjuvant use of Tagrisso, which would strengthen its stronghold across the spectrum of EGFR-mutated NSCLC yet further.

3. Adjuvant nivolumab significantly improves DFS in locally advanced head and neck cancer[10-12]

Phase 3 NIVOPOSTOP trial positions post-operative nivolumab plus cisplatin and radiotherapy as a potential new standard of care.

Cisplatin plus chemotherapy has been the standard of care for resected locally advanced squamous cell carcinoma of head and neck (SCCHN) for more than 20 years. In January 2025, GORTEC announced that the Phase 3 NIVOPOSTOP trial had met its primary endpoint. At ASCO 2025, investigators presented the efficacy and safety results. This marks the first therapy in decades to outperform the cisplatin-RT backbone in this setting.

Key ASCO findings

At three years, disease-free survival (DFS) was 63.1% with nivolumab plus chemoradiotherapy (CRT) vs. 52.5% with CRT alone, corresponding to a 24% relative reduction in the risk of recurrence or death (HR 0.76; P = 0.034). The benefit was consistent across all-comers, including PD-L1 expression levels and key high-risk pathological features. Notably, locoregional recurrence was reduced from 20% to 13% (HR 0.63), highlighting improved local disease control. OS data remain immature, though early trends favor nivolumab (3-year OS probability: 74.2% vs. 67.8%). The safety profile of the nivolumab regimen was manageable. However, adding nivolumab to CRT was associated with increased acute toxicity: grade 4 adverse events occurred in 13.1% of patients vs. 5.6% with CRT alone until 100 days after CRT, and then 1.2% vs. 0% up to 9 months.

Market impact

NIVOPOSTOP breaks a decades-long therapeutic impasse in high-risk, resected LA-SCCHN. Clarivate expects Bristol Myers Squibb to seek regulatory approval based on these promising clinical data, potentially positioning Opdivo as the first PD-1 inhibitor as an adjuvant therapy, extending its role beyond recurrent or metastatic (R/M) disease[11]. Although the eligible population is limited to resectable, cisplatin-eligible patients with high-risk features, the clinical impact could be practice-changing. Notably, these results emerge alongside positive perioperative data for Keytruda from the KEYNOTE-689 trial[12]. Keytruda is already under FDA priority review with PDUFA date of June 23, 2025, both drugs are advancing toward redefining the SOC in LA-SCCHN. Another consideration is that NIVOPOSTOP trial only recruited patients in Europe and Bristol Myers Squibb has not yet revealed their regulatory filling plans. Clarivate believes that the earliest approved regimen has potential to capture significant market share, but long-term survival and safety/tolerability, especially in less fit or cisplatin-ineligible patients, will ultimately help secure an edge over competitors.

4. Perioperative IMFINZI plus FLOT improves EFS in gastric and gastroesophageal junction (GEJ) adenocarcinoma[13-14]

Imfinzi is poised to become the first anti-PD-L1 therapy to demonstrate clinical benefit in the perioperative setting for gastric adenocarcinoma, setting a new standard of care.

Despite advances in surgery and multi-agent chemotherapy, nearly 50% of patients with resectable gastric or gastroesophageal junction (GEJ) adenocarcinoma experience recurrence within two years.[14] In March 2025, AstraZeneca announced that phase 3 MATTERHORN trial has met the primary endpoint, significantly improving EFS when combined with the FLOT regimen in resectable, locally advanced gastric and GEJ adenocarcinoma. This landmark study is the first to demonstrate the synergistic role of immune-checkpoint inhibitors with standard chemotherapy in the perioperative setting, addressing a significant unmet need. The first EFS data were presented at ASCO 2025[13].

Key ASCO findings

After a median follow-up of 31.6 months in the Imfinzi group and 31.4 months in the placebo group, Imfinzi plus FLOT improved EFS by 29% compared to placebo plus FLOT (NR vs 32.8 months, HR 0.71, p<0.001). At 18 and 24 months, EFS rates in the Imfinzi arm were 73% and 67%, respectively, versus 64% and 59% in the placebo arm. Although OS data is still immature, two-year OS rates were 76% in the Imfinzi group and 70% in the placebo group. The safety profile was comparable across both arms.

Market impact

Clarivate anticipated that the significant EFS benefit observed in the MATTERHORN trial has potential to be practice-changing, given the limited treatment options for resectable early-stage gastric/GEJ adenocarcinoma. Clarivate forecasts regulatory approval for Imfinzi based on these clinical data, which would make it the first immune checkpoint inhibitor to be approved for perioperative treatment amidst high profile failure of Keytruda in 2023 (phase 3 KEYNOTE-585 trial). Imfinzi will be addressing high unmet need in this lucrative patient population, however, the addition of Imfinzi to multi-drug chemotherapy regimen (i.e. FLOT) could restrict use.

5. Adjuvant Opdualag failed to improve RFS in completely resected stage III-IV malignant melanoma[15-16]

Bristol Myers Squibb's Opdualag faces adjuvant malignant melanoma setback, despite its success in advanced melanoma.

Opdualag, a fixed-dose combination of nivolumab (PD-1 inhibitor) and relatlimab (LAG-3 inhibitor), approved as first-line treatment for unresectable or metastatic malignant melanoma was tested in the Phase 3 RELATIVITY-098 trial as adjuvant therapy for completely resected stage III-IV malignant melanoma, using the standard of care, nivolumab, as comparator. However, in February 2025, Bristol Myers Squibb, announced that this trial has failed to meet its primary endpoint of relapsed-free survival (RFS), but the safety profiles remain consistent[16]. The primary efficacy and safety data were presented at ASCO 2025[15].

Key ASCO findings

After a median follow-up of 23.4 months, Opdualag did not result in significant RFS benefit compared with Opdivo (not reached vs. 33.1 months; HR 1.01); 24-month RFS rate for experimental arm was 62% vs. 63.6%. These finding were consistent across study stratified subgroups. Secondary efficacy endpoints included OS and disease metastasis-free survival (DMFS), OS data was immature (148 events, 48% maturity), similar DMFS rates were observed in both treatment arms (24-month DMFS rates: 73.1% vs. 76.3%; HR 1.07). The safety profile was comparable with the previous findings of Opdualag in Phase 3 RELATIVITY-047 trial.

Market impact

Clarivate anticipates that these findings could impact Bristol Myers Squibb's efforts to move Opdualag's use beyond advanced malignant melanoma and thus, reinforces adjuvant anti-PD-1 monotherapy as the standard of care in this setting. However, the RELATIVITY-098 raise questions on mechanistically similar combinations in the pipeline—most notably, Regeneron's adjuvant fianlimab plus Libtayo, currently in Phase 3 (NCT05608291). On the contrary, Philogen's intralesional therapy, Nidlegy (Phase 3 Neo-DREAM and NCT02938299) and Moderna's mRNA-4157 vaccine (Phase 3 INTerpath-001 trial) have shown promising early-phase data.

6. AMPLITUDE delivers landmark rPFS benefit for AKEEGA in HRR-mutated mHSPC[17]

The strong radiographic progression-free survival (rPFS) benefit and positive OS trend pave the way for PARP inhibitors in the lucrative hormone-sensitive setting, despite lingering safety concerns.

Poly ADP-ribose polymerase (PARP) inhibitors have become the standard of care in metastatic castration-resistant prostate cancer (mCRPC) with homologous recombination repair (HRR) mutations. The Phase 3 AMPLITUDE trial is the first to evaluate a PARP inhibitor—Akeega, a fixed-dose combination of niraparib and abiraterone—in the earlier setting of HRR-mutated metastatic hormone-sensitive prostate cancer (mHSPC), a population with significant market potential. Initial results were revealed at ASCO 2025[17].

Key ASCO findings

AMPLITUDE met its primary endpoint, with Akeega significantly reducing the risk of radiographic progression or death compared to abiraterone by 48% in patients with BRCA mutations (median rPFS NE vs. 26 months, P = 0.0001) and by 37% in the broader HRR-mutated population (median rPFS NE vs. 29.5 months, P = 0.0001). Time to symptomatic progression also improved significantly in both subgroups (HR 0.44 for BRCA, P = 0.0001; HR 0.50 for HRR mutated, P < 0.0001). OS data remain immature (~50% of events), but interim analyses favored Akeega (HR 0.75 in BRCA, 0.79 in HRR mutated). Safety was consistent with prior experience in MAGNITUDE, with higher rates of grade 3/4 treatment-emergent adverse events (75% vs. 59%) and discontinuations (15% vs. 10%) versus abiraterone.

Market impact

Clarivate anticipates that AMPLITUDE's positive findings will support a label expansion of Akeega in HRR-mutated mHSPC, a lucrative setting owing to a larger patient population than first-line mCRPC and currently untapped by PARP inhibitors. The added toxicity remains a concern especially in a setting where patients typically remain on therapy longer but the strong rPFS benefitin BRCA-mutated patients, who face poorer outcomes, makes earlier use more compelling in this subgroup. If approved, Clarivate believes that Akeega's first-mover advantage could give it a strategic edge, positioning it to capture the 20-30% of patients with HRR mutations. However, should Pfizer's upcoming TALAPRO-3 trial read-out be also positive, Clarivate anticipates that prescribing preference could shift towards Talzenna, whose open-label combination with enzalutamide may offer greater dosing flexibility and tolerability in clinical practice.

7. ENHERTU plus PERJETA shows strong PFS benefit versus THP in first-line HER2-positive metastatic breast cancer[18-20]

Enhertu's commercial potential in HER2-positive breast cancer could expand significantly based on this promising clinical data.

AstraZeneca and Daiichi Sankyo's antibody-drug conjugate (ADC) Enhertu is approved in the major markets for metastatic HER2-positive breast cancer patients who have received a prior anti-HER2-based regimen in the metastatic setting, or in the neoadjuvant or adjuvant setting and have progressed during or within six months of completing therapy. In April 2025, the companies announced that the phase 3 DESTINY-Breast09 trial, evaluating Enhertu plus pertuzumab in first-line metastatic HER2-positive patients, had met its prespecified endpoint of improvement in PFS compared with a taxane, trastuzumab and pertuzumab (THP), data were presented for the first time at ASCO 2025[18,19,20].

Key ASCO findings

Compared with the standard of care regimen THP, Enhertu demonstrated a median PFS of 40.7 months (vs. 26.9 months) in the HER2-positive population (HR 0.56, P < 0.0001). The PFS benefit was consistent across prespecified subgroups, including patients with prior exposure to HER2 therapies (median PFS of 38.0 vs. 21.5 months) and HR status (median PFS in HR-positive patients of 38.0 vs. 27.7 months and in HR-negative patients of 40.7 vs. 22.6 months). At this first interim analysis, OS data (secondary endpoint) were immature but trended favorably for Enhertu (HR 0.84). The safety profile of Enhertu was consistent with earlier reports; drug-related fatal interstitial lung disease was reported in 2patients (0.5%).

Market impact

DESTINY-Breast09 is the first trial in more than a decade to demonstrate superior efficacy compared with the standard of care across a broad first-line HER2-positive population. These potentially practice-changing data could position Enhertu plus pertuzumab as the new first-line treatment of choice for patients with metastatic HER2-positive breast cancer, according to Clarivate. Given the impressive efficacy shown, Clarivate expects the approval of Enhertu plus pertuzumab in the first-line HER2-positive breast cancer setting. However, questions remain regarding the appropriate treatment duration of Enhertu, selection of patients who would most benefit from front-line treatment and optimal sequencing of therapies. Additionally, the toxicities associated with Enhertu primarily interstitial lung disease could constrain the uptake of this regimen in the first-line setting.

8. TRODELVY in combination with KEYTRUDA significantly improves PFS in first-line triple-negative breast cancer[21-24]

Primary efficacy data from the pivotal Phase 3 ASCENT-04/KEYNOTE-D19 can help Trodelvy to move into front line triple-negative breast cancer (TNBC).

There remains an unmet need for patients with previously untreated PD-L1-positive advanced TNBC. Presently, the standard of care is immune checkpoint inhibitors in combination with chemotherapy. However, approximately 50% of patients do not receive a second-line therapy, highlighting the need for improved upfront treatment regimens.[22] Gilead and Merck's pivotal ASCENT-04/KEYNOTE-D19 trial is evaluating the efficacy of Trodelvy in combination with Keytruda in patients with locally advanced or metastatic TNBC. In April 2025, Gilead announced that this trial has met its primary endpoint of PFS.[23] Data were presented at ASCO 2025.[21]

Key ASCO findings

At a median follow-up of 14 months, the median PFS for patients treated with Trodelvy plus Keytruda was 11.2 months, compared with 7.8 months for those treated with chemotherapy in combination with Keytruda (HR 0.65, P < 0.001). This PFS benefit, favoring Trodelvy plus Keytruda, was consistent across most prespecified subgroups, however, this PFS benefit was not seen in patients with prior (neo) adjuvant anti-PD-(L)1 therapy. These finding warrants caution due to wide confidence intervals, resulting from the small subgroup of 20 patients. OS data, a key secondary endpoint, were immature; however, investigators observed a favorable early trend toward OS improvement with Trodelvy plus Keytruda. Although the median duration of treatment was longer in the experimental arm, the number of grade ≥ 3 treatment-emergent adverse events were similar (71% vs. 70%). No additive toxicity was observed with the combination, and the safety profile of the individual agents were consistent with earlier reports.

Market impact

The reported efficacy of Trodelvy plus Keytruda suggests that this combination could offer meaningful benefit to patients with PD-L1-positive advanced TNBC. Although the trial investigators have described this study as practice-changing, offering a chemotherapy-free first-line treatment for this patient population, the reported median PFS for the control arm, chemotherapy plus Keytruda, underperformed when compared to historical data. Approximately 40% of triple-negative breast cancer is PD-L1-positive[24] and label expansion to the first-line population could significantly expand the currently approved second-line FDA label for Trodelvy. Clarivate expects Trodelvy plus Keytruda to secure approval as a first-line treatment for PD-L-1 positive TNBC based on these data. Interestingly, Gilead also has announced that ASCENT-03 trial evaluating Trodelvy with chemotherapy in PD-L1 negative TNBC has demonstrated highly statistically significant and clinically meaningful PFS improvement which could further solidify Trodelvy's position in TNBC.

9. Switching standard endocrine therapy to camizestrant in 1L metastatic HR-positive, HER2-negative breast cancer with emergent ESR1 mutations significantly improves PFS[25-27]

SERENA-6 yielded positive data for camizestrant but the key secondary endpoints of PFS2 and OS will dictate the clinical utility of this novel strategy.

Acquiring ESR1 mutations confers resistance to aromatase inhibitors (AI). In February 2025, AstraZeneca revealed that the Phase 3 SERENA-6 trial significantly improved PFS when switching an AI (anastrozole or letrozole) to the oral selective estrogen receptor degrader camizestrant in first-line patients with an ESR1 mutation detected by ctDNA prior to clinical progression.[25] Upon detection of the ESR1 mutation, patients continued treatment with any of the approved CDK4/6 inhibitors given with either camizestrant or an AI (control arm) until clinical disease progression. At ASCO 2025, data from this trial were unveiled.[26,27]

Key ASCO findings

Compared with AI plus CDK4/6 inhibitor treatment continuation, switching the endocrine therapy backbone to camizestrant showed a median PFS improvement exceeding six months (9.2 vs. 16.0 months; HR 0.44, P < 0.00001). Patients switched to camizestrant also had significantly longer time to health deterioration. PFS2—a key second endpoint—remains immature but showed an encouraging trend towards improvement in the camizestrant arm (HR 0.52, P = 0.0038). OS, another key secondary endpoint, remains immature.
The safety profile was manageable and consistent with previous data.

Market impact

While the Phase 3 SERENA-6 trial met its primary endpoint of improving PFS, uncertainty remains as to whether these data will suffice to seek and gain regulatory approval or if additional long-term PFS2 and OS data will be required. Patients progressing on the control arm can be given additional endocrine therapies like Orserdu (approved for ESR1-mutant patients); therefore, results for PFS2 (and most crucially OS, to address the imbalance in the number of subsequent therapies between study arms) will be key to determine if this treatment strategy is clinically superior versus current treatment algorithms. If camizestrant is approved based on this trial, its use may be limited by the requirement for serial ctDNA testing.

10. Relacorilant plus nab-paclitaxel significantly improves PFS and OS in platinum-resistant ovarian cancer (PROC)[28-29]

Positive results from the ROSELLA trial set the stage for regulatory filings, offering new hope for the treatment of PROC.

Historically, platinum-resistant ovarian cancer has been treated with single-agent chemotherapy, with or without bevacizumab. The approval of Elahere in 2022 marked the only significant advancement in this setting, establishing the ADC as the SOC for patients with high folate receptor-alpha levels. Despite this progress, a substantial unmet need remains for the broader population of PROC patients, as no new effective therapies are available to them. At ASCO 2025, the positive results from the ROSELLA trial were presented for the first time[28], highlighting the efficacy of relacorilant plus nab-paclitaxel for PROC, with no need for biomarker selection.

Key ASCO findings

The combination of relacorilant with nab-paclitaxel significantly improved PFS compared to nab-paclitaxel alone, achieving a median PFS of 6.54 months vs. 5.52 months (HR 0.70, P = 0.0076). Results from a pre-specified interim analysis showed that adding relacorilant reduced the risk of death by 31%, extending the median OS to 16.0 months compared to 11.5 months for nab-paclitaxel alone (HR 0.69, P = 0.0121). Adverse events were similar across both arms when adjusted for nab-paclitaxel exposure[29].

Market impact

Based on these positive results, Corcept Therapeutics has announced that they plan to seek approval in the United States and Europe. The combination of relacorilant and nab-paclitaxel has the potential to become the new standard treatment for PROC patients, without requiring biomarker selection. However, while relacorilant will target a broader population compared to the FRα-targeted ADC Elahere, the PROC pipeline includes several promising therapies in late-phase development. Hence, Clarivate expects that this may lead to a fragmented market and potentially limit the uptake of the relacorilant combination in this setting.

11. IMDELLTRA significantly improved OS in second-line SCLC (DeLLphi-304)[30-33]

Game changing interim results of DeLLphi-304 poised to cement Imdelltra as second-line standard of care in SCLC.

Imdelltra, a first-in-class bispecific T-cell engager (BiTE) immunotherapy, received FDA accelerated approval in 2024 for the treatment of SCLC patients progressing on or after platinum-based chemotherapy. This approval was based on the promising activity demonstrated by Imdelltra in previously treated SCLC patients in a single-arm Phase 2 DeLLphi-301 trial[30]. In April 2025, Amgen announced that the Phase 3 DeLLphi-304 trial which is evaluating Imdelltra vs. chemotherapy in previously treated SCLC patients met primary endpoint of OS at a planned interim analysis[31]. First primary data from the confirmatory DeLLphi-304 study were unveiled at ASCO 2025.

Key ASCO findings

In the Phase 3 DeLLphi-304 study, Imdelltra demonstrated a median OS of 13.6 months vs. 8.3 months with chemotherapy (HR 0.60, P<0.001). The median PFS was 4.2 vs. 3.7 months (HR 0.71, P = 0.002), ORR was 35% vs. 20%, and median DOR was 6.9 vs. 5.5 months, respectively, in the Imdelltra and chemotherapy group. Overall, Imdelltra showed a favourable safety with class-specific adverse events of CRS and ICANS, occurring infrequently and generally of low grade, making them manageable. Grade ≥3 treatment-related adverse events were reported in 27% of patients receiving Imdelltra versus 62% in the chemotherapy group. Treatment discontinuations due to treatment-related adverse events were also lower with Imdelltra (3% vs. 6%)[32].

Market impact

The relapsed or refractory SCLC segment remains largely underserved, with a five-year survival rate of just 3% for patients with recurrent or metastatic SCLC33. Imdelltra, as the first and only targeted therapy approved for previously treated SCLC, is poised to significantly expand Amgen's presence in this tough to tame segment, bolstered by the exceptional survival benefit observed in the DeLLphi-304 trial. Amgen intends to use these pivotal results and potentially paving the way for conversion of accelerated approval to full approval. Additionally, Amgen is advancing a series of Phase 3 DeLLphi trials to assess Imdelltra in multiple SCLC treatment settings, further aiming to solidify its position in the SCLC landscape.

12. BRAFTOVI triplet combination prolongs overall survival in BRAF V600E-mutated metastatic colorectal cancer[34-38]

Braftovi is expected to secure full regulatory approval from FDA as a first-line treatment for BRAF V600E-mutated metastatic colorectal cancer, following practice-changing results from the BREAKWATER trial.

BRAF V600E mutations occur in 8–12% of metastatic colorectal cancer cases and are linked to poor prognosis and limited response to standard first-line therapies[36]. Braftovi, a selective BRAF inhibitor, received FDA accelerated approval in December 2024 in combination with Erbitux (cetuximab) for first-line use based on ORR (co-primary endpoint) and durability of response in the Phase 3 BREAKWATER trial[37]. Primary analysis of PFS (co-primary endpoint) and updated interim analysis of OS (secondary endpoint) were presented at ASCO 2025[34].

Key ASCO findings

The triplet combination of Braftovi, Erbitux and mFOLFOX6 delivered significant and clinically meaningful improvements in both PFS and OS vs. control. Median PFS improved to 12.8 months from 7.1 months (HR 0.53, P<0.0001), and ORR reached 65.7% vs. 37.4% for control. Median OS doubled to 30.3 months in the experimental arm vs 15.1 months in the control arm (HR 0.49, P<0.0001). The Braftovi plus Erbitux doublet showed numerically improved OS (19.5 months) over control and a more favorable safety profile. The safety profile of the triplet was consistent with expectations and considered manageable.

Market impact

BREAKWATER's unprecedented survival results represent a major progress in first-line treatment for BRAF V600E-mutant metastatic colorectal cancer. By doubling OS and significantly improving PFS, the triplet regimen sets a new benchmark. Pfizer announced that these results have been shared with the FDA to potentially support regulatory conversion to full approval.[38] These findings are likely to reshape global clinical guidelines and establish the triplet combination as preferred frontline therapy for this subgroup, while the doublet may offer an option for patients unable to tolerate chemotherapy.

Key ASCO 2025 takeaways from Mainland China

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13. The 'DeFu' combination demonstrates significant PFS improvement over PD-1 inhibitors in first-line advanced squamous NSCLC[39-45]

AnDeWei plus FuKeWei poised to reshape first-line sqNSCLC landscape with superior efficacy and accessibility.

Squamous non-small cell lung cancer (sqNSCLC) remains a challenging subtype in Mainland China, primarily due to the low prevalence of actionable driver mutations—only 13% compared to 61.4% in adenocarcinoma[41]. As a result, PD-1 inhibitors have become the mainstay of first-line therapy[42]. According to Clarivate's research BeOne's BaiZean (tislelizumab) is the patient share leader in this segment[43]. While Chinese guidelines recommend pembrolizumab monotherapy as the only Grade 1A option for PD-L1–positive advanced sqNSCLC, clinical outcomes highlight the ongoing need for more effective and durable treatment options [44,45]. At ASCO 2025, CTTQ presented compelling data from two late-phase studies evaluating the efficacy of AnDeWei (benmelstobart, a PD-L1 inhibitor), in combination with FuKeWei (anlotinib, a multi-targeted anti-angiogenic agent), in the first-line treatment of advanced sqNSCLC.

Key ASCO findings

In the phase 3 TQB2450-III-12 trial, benmelstobart plus chemotherapy followed by sequential benmelstobart plus anlotinib significantly improved median PFS (10.12 vs. 7.79 months; HR=0.64; P=0.0038), ORR (71.9% vs. 65.1%), and median DoR (9.69 vs. 8.34 months; HR=0.58; P=0.0091) compared to tislelizumab-based therapy.

Interim results from the CAMPASS study further supported these findings. Benmelstobart plus anlotinib significantly prolonged median PFS compared with pembrolizumab plus placebo (11.0 vs. 7.1 months; HR=0.70; P = 0.0057). Subgroup analyses showed enhanced benefit in patients with squamous histology (median PFS: 11.0 vs. 6.9 months; HR=0.63) and PD-L1 expression ≥50% (median PFS: 13.3 vs. 7.2 months; HR=0.60). Confirmed ORR was also higher in patients receiving the combination (57.3% vs. 39.6%; P < 0.001). Safety was manageable across studies, with low discontinuation rates due to adverse events.

Market impact

Current first-line treatments for advanced sqNSCLC in Mainland China deliver limited clinical benefit, hindered by a low prevalence of actionable mutations and, in some cases, high treatment costs, resulting in poor outcomes and a clear need for more effective and accessible treatment options. The DeFu combination offers a clinically superior and potentially more accessible alternative. Its dual mechanism—targeting both immune evasion and angiogenesis—addresses key resistance pathways and has demonstrated consistent efficacy across PD-L1 subgroups and squamous histology. With an NDA submitted to the NMPA in April 2025, the DeFu regimen is well positioned to challenge the dominance of PD-1 inhibitors in this space. If approved, it could become the preferred frontline option for advanced sqNSCLC patients, delivering both clinical and economic value in an underserved population.

14. Becotatug vedotin shows OS benefit in heavily pretreated advanced nasopharyngeal carcinoma (NPC)[46-50]

With improved survival outcomes in third-line recurrent or metastatic (R/M) NPC, becotatug vedotin is poised to redefine the treatment paradigm in this underserved segment.

Becotatug vedotin is a first-in-class EGFR-targeting ADC being developed by Lepu Biopharma for the treatment of R/M NPC, a malignancy with high prevalence in Mainland China [47,48]. In the third-line setting, where patients have typically progressed following platinum-based chemotherapy and immune checkpoint inhibitors, there is currently no established standard of care. Available treatment options are limited to single-agent chemotherapy, which is often associated with poor response rates and minimal survival benefit, Underscoring a significant unmet clinical need in this population. Initial findings from a randomized phase 2 trial evaluating becotatug vedotin in patients with heavily pretreated R/M NPC were presented at ASCO 2025.

Key ASCO findings

Becotatug vedotin showed a significantly higher ORR (as assessed by BICR) of 30.2%, nearly three times higher than that observed in the chemotherapy arm (difference: 18.7%, 95% CI: 7.0%–30.5%, P=0.0025). Median PFS was also notably prolonged at 5.8 months vs. 2.8 months (HR=0.63; P=0.0146). Interim OS data showed a median OS of 17.1 months for becotatug vedotin compared with 12.0 months for chemotherapy (HR=0.73), despite patients having received a median of three prior lines of therapy. The safety profile was manageable, with grade ≥3 treatment-related adverse events (TRAEs) occurring in 45.3% of patients in the ADC arm versus 50.6% in the chemotherapy arm. Importantly, the incidence of severe leukopenia was substantially lower with becotatug vedotin (9.3% vs. 35.6%).

Market impact

Based on these data, Lepu Biopharma submitted an NDA to the NMPA in September 2024[49], seeking approval for becotatug vedotin in the third-line treatment of R/M NPC. Simultaneously, a phase 3 trial is underway—evaluating the ADC in the second-line setting—underscoring the company's intent to expand its clinical utility and move the therapy earlier in the treatment continuum[50]. This strategic expansion not only positions becotatug vedotin as a potential first-in-class treatment in the later-line setting but also lays a foundation for broader adoption across multiple lines of therapy. If approved, it would become the first targeted agent to demonstrate a survival benefit in this heavily pretreated population, offering a much-needed alternative to conventional chemotherapy and setting a new benchmark in a historically underserved patient segment.

15. ADIXI exhibits promising activity across the HER2 expression spectrum in locally advanced and metastatic gastric or GEJ cancer[51-54]

Clinical and commercial momentum builds for ADIXI following promising results.

Trastuzumab in combination with chemotherapy has long been the standard of care in patients with HER2-positive locally advanced and metastatic gastric and GEJ cancer. However, treatment options remain limited for patients with HER2-low expressing tumors, who are typically less responsive to conventional HER2-targeted therapies. At ASCO 2025, findings from the phase 2/3 trial were presented, evaluating disitamab vedotin in combination with toripalimab and chemotherapy—with or without trastuzumab—in patients with HER2-overexpressing and HER2-median / low-expressing locally advanced or metastatic gastric / GEJ cancer.

Key ASCO findings

At a median follow-up of 13.2 months, patients with HER2-overexpressing tumors receiving disitamab vedotin (2.5 mg/kg) plus toripalimab plus trastuzumab (n=17) achieved an ORR of 82.4%, vs. 68.8% with toripalimab plus trastuzumab plus CAPOX (n=16). Median PFS was not reached in the treatment group, suggesting a trend toward durable clinical benefit.
In the HER2-median / low–expressing cohort, stage 1 results at 10.4 months showed a confirmed ORR of 72.0% with disitamab vedotin (2.5 mg/kg) plus toripalimab plus CAPOX, vs.47.8% in patients receiving toripalimab plus CAPOX. Median PFS was 9.9vs. 7.2 months. Stage 2 dose optimization study reinforced these findings. At a median follow-up of 7 months, patients receiving disitamab vedotin (2.5 mg/kg) plus toripalimab plus CAPOX had a confirmed ORR of 71.4%, while those receiving a lower dose of 2.0 mg/kg achieved 66.7%, compared with 56.3% in the control group receiving toripalimab plus CAPOX only. Median PFS was not reached in the 2.5 mg/kg and control arms. Overall, the 2.5 mg/kg dose demonstrated consistent benefit. ADIXI had a manageable safety profile, with similar rates of grade ≥3 TRAEs across arms.

Market impact

Remegen is conducting a phase 3 study to evaluate disitamab vedotin with tislelizumab and chemotherapy as a first-line treatment for HER2-median / low expressing (IHC 2+ and IHC 1+) advanced gastric and GEJ cancers[52]. While ADIXI is already approved for HER2-overexpressing gastric cancer in later-line settings, its inclusion in National Reimbursement Drug List (NRDL) since 2021 has significantly improved access and affordability[53,54]. Data from the ongoing phase 3 study is expected to support label expansion into a broader HER2-expressing population, particularly those underserved by existing HER2-targeted therapies.
The use of domestically developed drug—both disitamab vedotin and tislelizumab—further enhances the cost-effectiveness and accessibility of this regimen in mainland China. Together, these developments strengthen ADIXI's potential to reshape the HER2 treatment landscape in gastric and GEJ cancers.

16. Sichuan Kelun-Biopharm's JIATAILAI shows high response rates and prolonged PFS in treatment-naïve TNBC, independent of PD-L1 status[55-59]

JIATAILAI enters the frontline segment with encouraging findings in the OptiTROP-Breast05 study.

Treatment-naive metastatic TNBC remains a highly underserved patient segment in mainland China. Current first-line options include chemotherapy alone or in combination with immunotherapy for PD-L1–positive patients, and PARP inhibitors for those with BRCA mutations. However, most of these regimens offer limited clinical benefit, with PFS ranging from 5-7 months[56, 57,] highlighting the need for more effective treatment alternatives, particularly in PD-L1 negative (combined positive score [CPS] <10) patients. SKB presented encouraging findings from one arm of the phase 2 OptiTROP-Breast05 trial at ASCO 2025.

Key ASCO findings

In OptiTROP-Breast05 study, sacituzumab tirumotecan demonstrated promising ORR and PFS benefits as first-line treatment in 41 patients with advanced or metastatic TNBC, of whom 78% had a PD-L1 combined positive score (CPS) <10. The study met its primary endpoint, with an ORR of 70.7% and a DCR of 92.7%. Median PFS (mPFS) was 13.4 months, and DoR of 12.2 months. Study outcomes were consistent in the PD-L1–negative subgroup (CPS <10), with an ORR of 71.9%, DCR of 93.8%, and mPFS of 13.1 months. The 12-month PFS rate was 64.6% (95% CI: 45.0%, 78.7%) in the overall pool and 59.1% (95% CI: 37.1%, 75.7%) in the PD-L1–negative subgroup. The safety profile was manageable, with no treatment-related deaths or reported cases of neuropathy or interstitial lung disease/pneumonitis.

Market impact

As the first domestically developed TROP2-targeted ADC, JIATAILAI entered the Chinese market in December 2024, for third or later-line treatment of metastatic TNBC. Its compelling phase 2 data in treatment-naive patients positions it as a strong contender for earlier-line use. While its closest competitor, sacituzumab govitecan (Gilead's Trodelvy), is further along in global development and recently reported positive topline results from the phase 3 ASCENT-03 trial in PD-L1–negative or immunotherapy-ineligible patients[58], JIATAILAI offers a domestically developed alternative with encouraging efficacy and a favorable safety profile. Given the limited availability of effective and affordable TNBC treatments in mainland China, JIATAILAI is well-positioned for inclusion in the National Reimbursement Drug List (NRDL) by 2026—a move that would significantly improve patient access and enhance its commercial potential in this market[59]. The ongoing phase 3 trial will be instrumental in securing first-line regulatory approval from the NMPA, further strengthening JIATAILAI's role in the evolving treatment landscape for TNBC in mainland China.

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