ESMO 2025

Year on year, the society continues to grow and lead innovations in oncology, prioritising education, scientific dissemination, and supporting members in their journey

Congress Review

Review of the European Society for Medical Oncology (ESMO) Congress 2025

Location:	Berlin, Germany
Date:	17th–21st October 2025
Citation:	EMJ Oncol. 2025;13[1]:10-22. https://doi.org/10.33590/emjoncol/GBXP9968

THE EUROPEAN Society for Medical Oncology (ESMO) Congress 2025 took place in Berlin, Germany, a dynamic epicentre known for its blend of innovation, culture, and historical significance. Home to approximately 3.7 million people, Berlin is Germany's largest and most diverse city, offering a vibrant backdrop for an international gathering of oncologists, researchers, and healthcare professionals.

Fabrice André, the ESMO President, opened the Congress, highlighting the society's 50th anniversary. Year on year, the society continues to grow and lead innovations in oncology, prioritising education, scientific dissemination, and supporting members in their journey, now with over 45,000 members. André highlighted the five integral pillars of ESMO: new drugs, strategies of treatment and care, delivery of care, toxicity management, and prevention. Looking to future initiatives, he spotlighted the society's desire to simplify clinical research, revitalise academic research, and develop individuals' careers. He stressed the need to invest in personalised prevention and post-cancer care, as well as fostering responsible integration of AI and digital tools, and developing a health economics approach.

So, what are the highlights of this year's programme? Scientific Co-Chairs Myriam Chalabi, Netherlands Cancer Institute, Amsterdam, the Netherlands; and Toni Choueiri, Dana-Farber Cancer Institute, Boston, Massachusetts, USA, took the stage to outline them. The overarching theme of this Congress was one of broken records. A record 5,677 abstracts were submitted, over 600 more than last year's 5,030. Attendees also reached an all-time high at 35,676, a steep increase from 33,830 the previous year. Of the 5,677 submitted abstracts, 2,926 were accepted for presentation across presidential symposia (12), proffered papers (158), mini orals (213), posters (1,894), and ePosters (649). In total, the programme featured 2,181 sessions, including three major presidential symposia showcasing practice-changing, practice-informing, and forward-looking research. Read on for an in-depth coverage of the presentations in the presidential symposia.

During the opening ceremony, several prestigious awards recognised individuals for their leadership and contributions to oncology. Thierry Conroy, University of Lorraine, Nancy, France, recipient of the ESMO Award, spoke on the progress made in pancreatic cancer research, improving pancreatic cancer's 5-year survival from under 3% in 2000 to 13% in 2025. Christina Curtis, Stanford University, Palo Alto, California, USA, recipient of the ESMO Award for Translational Research, presented

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on harnessing AI to enhance the prediction of cancer progression and personalise treatment. Rolf Stahel, President of the European Thoracic Oncology Platform – International Breast Cancer Study Group (ETOP IBCSG) Partners Foundation, who received the ESMO Lifetime Achievement Award, reflected on his longstanding commitment to mentorship, teamwork, and the development of initiatives such as the ESMO Clinical Practice Guidelines and the ETOP IBCSG Partners Foundation. The final awardees were Natasha Leighl, University of Toronto, Canada, who received the ESMO Women for Oncology Award, and Glenda Ramos Martinez, Sociedad de Lucha Contra el Cancer, Guayaquil, Ecuador, who received the ESMO Oncologist of the Year Award.

The ESMO Congress 2025 was a landmark event, standing at the forefront of major scientific advances and reaffirming the collective commitment to improving outcomes for patients around the world. Read on for the major takeaways from ESMO 2025, and make sure to join us next year for ESMO 2026 in Madrid, Spain, from 23rd–27th October 2026.

> **A record 5,677 abstracts were submitted, over 600 more than last year's 5,030. Attendees also reached an all-time high at 35,676, a steep increase from 33,830 the previous year**

Anthracycline-Free Regimen Improves Outcomes in Early HER2+ Breast Cancer

INTERIM results from the Phase III DESTINY Breast11 trial (291O), presented at the ESMO 2025 Congress, indicate that trastuzumab deruxtecan (T DXd) followed by paclitaxel, trastuzumab, and pertuzumab (T DXd THP) significantly increased pathological complete response (pCR) rates compared with the standard anthracycline-based regimen in patients with high-risk HER2-positive early breast cancer (eBC).[1]

The trial evaluated two T DXd regimens, T DXd alone or T DXd THP, against dose dense doxorubicin and cyclophosphamide followed by THP (ddAC THP). The open-label, randomised, multicentre study enrolled adults with untreated high-risk disease (≥T3, node positive [N1–3], or inflammatory HER2-positive eBC). Treatments were administered in eight neoadjuvant cycles: T DXd (5.4 mg/kg every 3 weeks), T DXd THP (four cycles of T DXd followed by weekly paclitaxel plus 3-weekly trastuzumab and pertuzumab), or ddAC THP (A+C every 2 weeks for four cycles followed by THP). The primary endpoint was pCR (ypT0/is ypN0); secondary endpoints included event-free survival and safety.

By March 2025, 321 patients were randomised to T DXd THP and 320 to ddAC THP. The T DXd THP regimen achieved a pCR rate of 67.3% compared with 56.3% for ddAC THP, an absolute difference of 11.2% (95% CI: 4.0–18.3; p=0.003). Improvements were seen across hormone receptor subgroups: 61.4% versus 52.3% in hormone receptor-positive and 83.1% versus 67.1% in hormone receptor-negative disease. An early favourable trend for event-free survival was reported (hazard ratio: 0.56; 95% CI: 0.26–1.17).

Safety data showed lower rates of high-grade toxicity with T DXd THP. Grade ≥3 adverse events (AE) occurred in 37.5% (T DXd THP) versus 55.8% (ddAC THP) of patients, and serious AEs in 10.6% (T DXd THP) versus 20.2% (ddAC THP). Adjudicated interstitial lung disease or pneumonitis occurred in 4.4% (T DXd THP) versus 5.1% (ddAC THP), and left ventricular dysfunction occurred in 1.9% (T DXd THP) versus 9.0% (ddAC THP). No AEs prevented surgery in any treatment arm.

The results suggest that T DXd THP provides superior efficacy and improved tolerability compared with ddAC THP, supporting its potential as an anthracycline-free neoadjuvant option for high-risk HER2-positive eBC. The T DXd-only arm, which halted enrolment following Independent Data Monitoring Committee advice in 2024, will be reported separately.

> **“The trial evaluated two T DXd regimens, T DXd alone or T DXd THP, against dose dense doxorubicin and cyclophosphamide followed by THP”**

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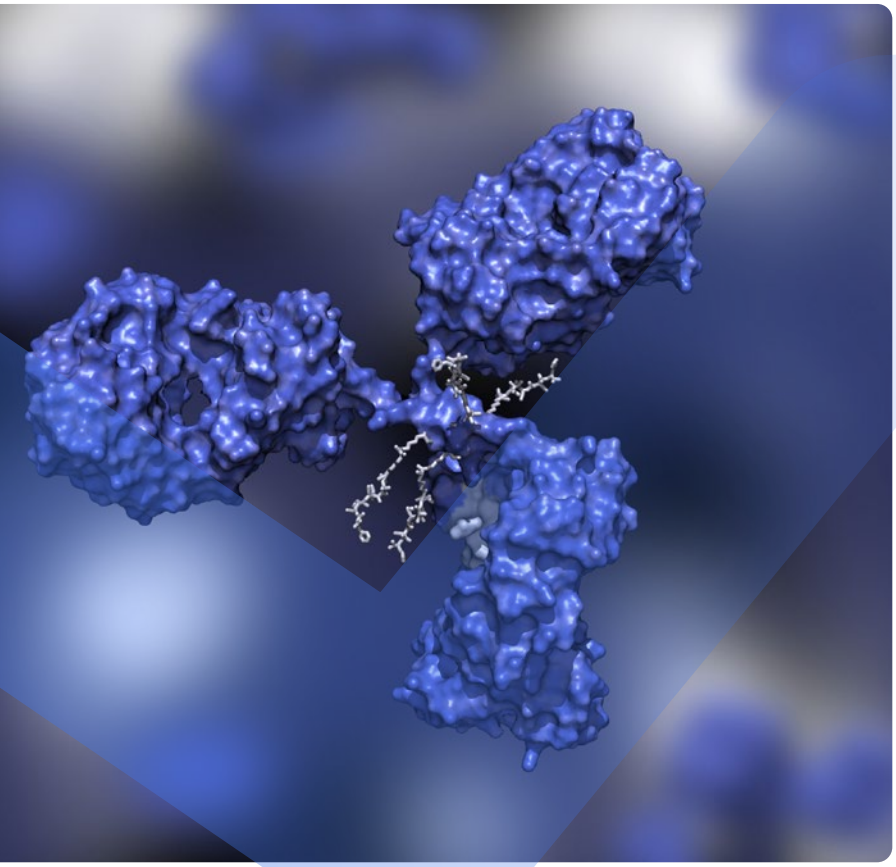
Trastuzumab Deruxtecan Outperforms Trastuzumab Emtansine in High-Risk HER2+ Early Breast Cancer

IN ONE of the most closely watched trials in early breast cancer, trastuzumab deruxtecan (T-DXd) has delivered a major step forward for patients with HER2-positive disease and residual invasive cancer after neoadjuvant therapy. Interim findings from the DESTINY-Breast05 Phase III trial, presented at the ESMO 2025 Congress, show that T-DXd cut the risk of invasive disease recurrence or death by more than half compared with the long-standing standard of care, trastuzumab emtansine (T-DM1).[2]

The open-label trial enrolled 1,635 patients with residual HER2-positive invasive breast cancer following neoadjuvant taxane-based chemotherapy and HER2-targeted therapy. Participants were randomised to receive either T-DXd (5.4 mg/kg) or T-DM1 (3.6 mg/kg) every 3 weeks for 14 cycles. After a median follow-up of nearly 30 months, T-DXd demonstrated a 53% reduction in the risk of invasive disease-free survival events (hazard ratio [HR]: 0.47; 95% CI: 0.34–0.66; p<0.0001) compared with T-DM1. The benefit was mirrored in disease-free survival results (HR: 0.47; 95% CI: 0.34–0.66; p<0.0001).

A trend towards improved brain metastasis-free interval was also observed with T-DXd (HR: 0.64; 95% CI: 0.35–1.17), highlighting its potential to delay or prevent central nervous system involvement, which is a growing concern in HER2-positive disease.

Safety outcomes were largely consistent with prior T-DXd studies. Grade ≥3 adverse events occurred in about half of patients in both groups (50.6% with T-DXd versus 51.9% with T-DM1). Interstitial lung disease was more frequent with T-DXd (9.6% versus 1.6%), though most cases were Grade 1–2; two Grade 5 events were reported.



Taken together, these interim data establish T-DXd as a new benchmark for post-neoadjuvant treatment in patients with high-risk HER2-positive early breast cancer, offering not just incremental but transformative improvement in outcomes for this challenging population.

> **T-DXd demonstrated a 53% reduction in the risk of invasive disease-free survival events compared with T-DM1**

Perioperative Enfortumab Vedotin–Pembrolizumab Sets New Standard for Muscle-Invasive Bladder Cancer

A STUDY presented at the ESMO 2025 Congress reported that adding perioperative enfortumab vedotin (EV) plus pembrolizumab to surgery significantly and meaningfully improves outcomes in patients with muscle-invasive bladder cancer (MIBC) who are cisplatin-ineligible.[3]

Radical cystectomy combined with pelvic lymph node dissection is the standard treatment for patients with MIBC who are cisplatin-ineligible. Perioperative therapy may improve outcomes in these patients. Therefore, researchers investigated the addition of perioperative EV plus pembrolizumab to standard treatment for MIBC.

The Phase III KEYNOTE-905/EV-303 study evaluated the efficacy and safety of perioperative EV plus pembrolizumab with radical cystectomy and pelvic lymph node dissection compared to radical cystectomy and pelvic lymph node dissection alone in adult patients with MIBC (T2-T4aN0M0 or T1-T4aN1M0) who were cisplatin-ineligible or declined cisplatin. Patients were randomised 1:1 to EV plus pembrolizumab (three cycles of EV 1.25 mg/kg on Day 1 and Day 8 plus pembrolizumab 200 mg on Day 1 every 3 weeks, followed by radical cystectomy and pelvic lymph node dissection, then six cycles of EV plus 14 cycles of pembrolizumab) versus control (radical cystectomy and pelvic lymph node dissection only). Therapy continued until disease progression, unacceptable adverse events, withdrawal of consent, or completion of planned treatment.

In total, 170 patients were randomised to EV plus pembrolizumab and 174 patients to control. Over 80% of patients were cisplatin-ineligible, as determined by the Galsky criteria. As of 6th June 2025, the median follow-up time was 25.6 months (range: 11.8–53.7). In this study, 149 patients (87.6%) underwent surgery in the EV plus pembrolizumab group and 156 (89.7%) in the control group.

The results revealed that EV plus pembrolizumab significantly improved event-free survival (hazard ratio: 0.40; 95% CI: 0.28–0.57; p<.001), overall survival (hazard ratio: 0.50; 95% CI: 0.33–0.74; p<.001), and pathological complete response rate (57.1% versus 8.6%; estimated difference: 48.3%; 95% CI: 39.5–56.5; p<.001) versus control. Treatment-emergent adverse events occurred in 100% of patients in the EV plus pembrolizumab arm (of which 71.3% were at least Grade 3), and in 64.8% of patients in the control group (of which 45.9% were at least Grade 3). The most frequent Grade ≥3 adverse events of special interest were severe skin reactions (11.4%) for pembrolizumab and skin reactions (10.8%) for EV.

> **EV plus pembrolizumab significantly improved event-free survival, overall survival, and pathological complete response rate**

In conclusion, the addition of perioperative EV plus pembrolizumab significantly improved event-free survival, overall survival, and pathological complete response rate in patients with MIBC who were predominantly cisplatin-ineligible. Additionally, the safety profile of EV plus pembrolizumab was manageable and consistent with prior reports. This is the first perioperative regimen to improve outcomes compared to standard treatment, and may become a new standard of care.

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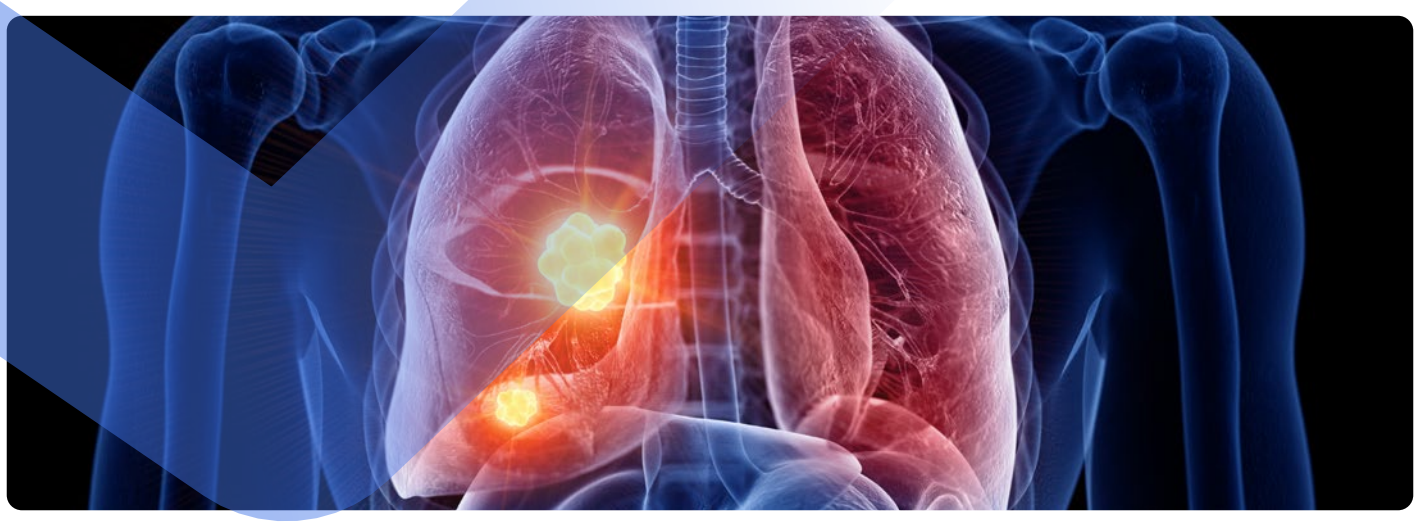

New Study Supports Ivonescimab for Squamous Lung Cancer

A RECENT Phase III study, presented at the ESMO 2025 Congress, has shown that ivonescimab combined with chemotherapy significantly improves progression-free survival (PFS) compared with tislelizumab plus chemotherapy in patients with untreated advanced squamous non-small cell lung cancer, regardless of programmed death-ligand 1 (PD-L1) expression.[4]

This trial included 532 patients with Stage IIIB–IV disease, randomised equally to receive ivonescimab or tislelizumab alongside paclitaxel and carboplatin for four cycles, followed by maintenance monotherapy. Randomisation was stratified by disease stage and PD-L1 tumour proportion score (TPS). The primary endpoint was PFS, assessed by an independent radiographic review committee in line with RECIST v1.1, with overall survival as a key secondary endpoint.

Baseline characteristics were balanced between the two groups, with 63.2% of patients presenting central tumours, 8.8% tumour cavitation, and 17.5% major blood vessel encasement. Ivonescimab plus chemotherapy demonstrated a statistically significant PFS improvement versus tislelizumab plus chemotherapy, with a hazard ratio (HR) of 0.60 (95% CI: 0.46–0.78; p<0.0001). Median PFS was 11.1 months in the ivonescimab arm versus 6.9 months in the tislelizumab arm. The benefit was consistent across key subgroups: patients with PD-L1 TPS <1% had a median PFS of 9.9 versus 5.7 months (HR: 0.55), while those with PD-L1 TPS ≥1% showed 12.6 versus 8.6 months (HR: 0.66). Safety profiles were comparable, with treatment-related serious adverse events reported in 32.3% and 30.2% of patients, and Grade ≥3 haemorrhagic events occurring in 1.9% and 0.8%, for the ivonescimab and tislelizumab groups, respectively.

These findings suggest that ivonescimab in combination with chemotherapy may represent a new first-line standard of care for patients with advanced or metastatic squamous non-small cell lung cancer, offering a meaningful extension in PFS while maintaining a manageable safety profile.

> **These findings suggest that ivonescimab in combination with chemotherapy may represent a new first-line standard of care**

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Phase III OptiTROP-Lung04 Trial Shows Sacituzumab Tirumotecan Extends Survival in *EGFR*-Mutated Non-small Cell Lung Cancer

A PHASE III trial presented at the ESMO 2025 Congress has shown that sacituzumab tirumotecan (sac-TMT), a novel TROP2-directed antibody–drug conjugate, delivers a significant survival advantage over standard platinum-based chemotherapy in patients with *EGFR*-mutated non-small cell lung cancer (NSCLC) who have progressed on EGFR tyrosine kinase inhibitors (TKI).[5]

The findings position sac-TMT as a promising new treatment option for a population with limited therapeutic alternatives.

The randomised, multicentre study enrolled 376 patients with advanced *EGFR*-mutated NSCLC who received prior third-generation EGFR TKI therapy, with or without platinum-based chemotherapy. Participants were randomised 1:1 to receive either sac-TMT monotherapy or a platinum doublet (pemetrexed plus carboplatin or cisplatin). The study's primary endpoint was progression-free survival (PFS), assessed by a blinded independent review committee, with overall survival (OS) as a key secondary endpoint.

At a median follow-up of 18.9 months, sac-TMT achieved a median PFS of 8.3 months compared with 4.3 months for chemotherapy (hazard ratio [HR]: 0.49; 95% CI: 0.39–0.62; p<0.0001). The 12-month PFS rate was 32.3% with sac-TMT versus 7.9% with chemotherapy. OS data also favoured sac-TMT, with a median OS not yet reached versus 17.4 months for chemotherapy (HR: 0.60; 95% CI: 0.44–0.82; p=0.0006). Adjusted OS analysis confirmed these findings (HR: 0.56; p=0.0002). The objective response rate was 60.6% for sac-TMT compared with 43.1% for chemotherapy, with a median response duration of 8.3 versus 4.2 months, respectively.

Treatment-related adverse events of Grade 3 or higher occurred in 49.5% of patients receiving sac-TMT and 52.2% receiving chemotherapy. Serious treatment-related adverse events were less frequent with sac-TMT (7.4% versus 17.0%), and no drug-related interstitial lung disease or pneumonitis was reported in either group.

According to the study chair, the results represent a major advancement in the post-TKI treatment landscape, as sac-TMT becomes the first TROP2-targeted antibody–drug conjugate to show both PFS and OS superiority over chemotherapy in this setting.

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Radioligand Therapy Improves Survival in Metastatic Prostate Cancer

AT THE ESMO 2025 Congress, the Phase III PSMAddition trial (LBA6) demonstrated that combining the radioligand [^{177}Lu]Lu-PSMA-617 with standard androgen deprivation therapy (ADT) and an androgen receptor pathway inhibitor (ARPI) significantly improved radiographic progression-free survival (rPFS) in patients with prostate-specific membrane antigen (PSMA)-positive metastatic hormone-sensitive prostate cancer (mHSPC).[6]

The trial involved 1,144 adults with treatment-naïve or minimally treated (≤45 days) mHSPC and at least one PSMA-positive metastatic lesion detected by [^{68}Ga]Ga-PSMA-11 PET/CT. Participants were randomised (1:1) to receive [^{177}Lu]Lu-PSMA-617 (7.4 GBq every 6 weeks, six cycles) plus ADT and ARPI, or standard ADT and ARPI alone. Randomisation was stratified by disease volume (high or low), age (≥70 or <70 years), and primary tumour treatment (yes or no). Patients in the control arm with centrally confirmed radiographic progression could cross over to [^{177}Lu]Lu-PSMA-617 if eligible.

At the second interim analysis (data cut-off: 13th January 2025; median follow-up: 23.6 months), the primary endpoint was met. rPFS was significantly improved in the [^{177}Lu]Lu-PSMA-617 arm, with 139 events (24.3%) compared with 172 (30.1%) in the control arm, yielding a hazard ratio of 0.72 (95% CI: 0.58–0.90; p=0.002). Median rPFS was not estimable in either arm. A positive trend in overall survival was observed (hazard ratio: 0.84, 95% CI: 0.63–1.13; p=0.125), with 85 events (14.9%) in the [^{177}Lu]Lu-PSMA-617 arm versus 99 (17.3%) in the control arm. The objective response rate also favoured the [^{177}Lu]Lu-PSMA-617 arm at 85.3% (95% CI: 79.9–89.6; n=224) versus 80.8% (95% CI: 74.8–85.8; n=213).

Safety findings were consistent with prior experience. Any adverse event (AE) occurred in 98.4% of patients receiving [^{177}Lu]Lu-PSMA-617 and 96.6% in controls. Grade ≥3 AEs were reported in 50.7% versus 43.0% in the control arm, and serious AEs in 31.9% versus 28.7% in the control arm. Dry mouth, mainly Grade 1–2, was the most common AE (41.0% Grade 1 and 4.8% Grade 2 versus 3.4% and 0.4% in controls). Grade ≥3 cytopenias occurred in 14.4% of patients receiving [^{177}Lu]Lu-PSMA-617 versus 5.0% in the control arm. Time to deterioration in quality of life, measured by Functional Assessment of Cancer Therapy-Prostate (FACT-P) and EuroQol-5 Dimension (EQ-5D), did not differ meaningfully between groups.

The findings establish that [^{177}Lu]Lu-PSMA-617 added to ADT and ARPI significantly improves rPFS in PSMA-positive mHSPC without notable impairment in safety or quality of life. Long-term follow-up for overall survival and durability of benefit is ongoing.

> **The findings establish that [^{177}Lu]Lu-PSMA-617 added to ADT and ARPI significantly improves rPFS in PSMA-positive mHSPC without notable impairment in safety or quality of life**

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Circulating Tumour DNA-Guided Atezolizumab Extends Survival in High-Risk Bladder Cancer

A NOVEL circulating tumour DNA (ctDNA)-guided approach to postoperative therapy has delivered a major advance for patients with muscle-invasive bladder cancer (MIBC). Interim results from the Phase III IMvigor011 trial (NCT04660344), presented at the ESMO 2025 Congress, show that adjuvant atezolizumab significantly improves both disease-free and overall survival compared with placebo in patients who test positive for ctDNA following radical cystectomy.[7]

The global, randomised, double-blind trial enrolled 761 patients with high-risk MIBC and no radiographic evidence of disease. Participants were entered into a year-long ctDNA surveillance programme beginning 6–24 weeks after surgery. Only those who tested ctDNA-positive, indicating the presence of minimal residual disease, were randomised 2:1 to receive either atezolizumab (1,680 mg every 4 weeks) or placebo for up to 12 cycles. Patients who remained ctDNA-negative throughout surveillance received no adjuvant treatment.

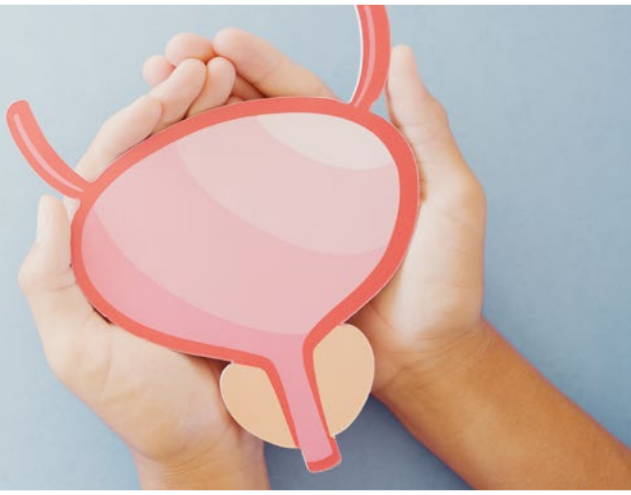
After a median follow-up of 16.1 months, atezolizumab reduced the risk of recurrence or death by 36% among patients who were ctDNA-positive compared with placebo (disease-free survival hazard ratio: 0.64; 95% CI: 0.47–0.87; p=0.0047). The overall survival benefit was also statistically significant, with a 41% reduction in mortality risk (hazard ratio: 0.59; 95% CI: 0.39–0.90; p=0.0131). Median disease-free survival was 9.9 months with atezolizumab versus 4.8 months with placebo, while the 12-month survival rate reached 85.1% in the atezolizumab arm compared with 70.0% for placebo.

Toxicities were manageable and in line with previous reports for atezolizumab. Grade 3–4 adverse events occurred in 28.5% of atezolizumab-treated patients versus 21.7% with placebo; treatment-related events were reported in 7.3% and 3.6%, respectively. Fatal treatment-related events were rare (1.8% versus 0%).

Importantly, for the 357 patients who remained persistently ctDNA-negative, the outcomes were excellent: 95.4% were disease-free at 1 year and 88.4% at 2 years, suggesting that these patients may safely avoid adjuvant therapy altogether.

By integrating molecular monitoring with precision immunotherapy, IMvigor011 marks a pivotal step towards personalising postoperative treatment in MIBC, offering therapy only when it's truly needed, while sparing others from unnecessary toxicity.

> **"By integrating molecular monitoring with precision immunotherapy, IMvigor011 marks a pivotal step towards personalising postoperative treatment in MIBC."**



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Circulating Tumour DNA-Guided De-escalation Reduces Toxicity in Stage III Colon Cancer

PRIMARY analysis of the circulating tumour DNA (ctDNA)-negative cohort from the randomised AGITG DYNAMIC-III trial, presented at the ESMO 2025 Congress, has demonstrated that ctDNA-guided de-escalation is feasible and substantially reduces oxaliplatin exposure and adverse events, with outcomes approaching standard management, especially for clinical low-risk tumours.[8]

The individual benefit of adjuvant chemotherapy is not well understood. Therefore, researchers sought to investigate whether post-surgery ctDNA testing could support risk-adjusted treatment selection and guide the de-escalation of adjuvant chemotherapy. The DYNAMIC-III study explored adjuvant chemotherapy de-escalation or escalation, informed by post-surgery ctDNA results.

In this multicentre, randomised, Phase II/III trial, patients with Stage III colon cancer who underwent tumour-informed ctDNA testing 5–6 weeks post-surgery were randomised to receive either ctDNA-guided or standard management. For patients who received ctDNA-guided management, ctDNA-negative results prompted adjuvant chemotherapy de-escalation: from 6 to 3 months of fluoropyrimidine or observation, from 3 months of doublet to single-agent fluoropyrimidine, or from 6 months of doublet to 3 months of doublet or single-agent fluoropyrimidine. In this study, the primary endpoint was 3-year recurrence-free survival.

> **ctDNA-guided de-escalation is feasible and reduces oxaliplatin exposure and adverse events, with outcomes approaching standard management**

In total, 968 patients were enrolled, of whom 702 (72.5%) were ctDNA-negative. Within this group, 353 patients were assigned to ctDNA-guided treatment management, and 349 to standard management. At a median follow-up of 45 months, 319 (90.4%) patients received ctDNA-guided per-protocol de-escalation.

The analysis revealed that ctDNA-guided treatment de-escalation reduced oxaliplatin-based chemotherapy use to 34.8%, compared to 88.6% with standard management ($p<0.001$). Additionally, ctDNA-guided treatment lowered Grade 3+ adverse events of special interest (6.2% versus 10.6%; $p=0.037$) and treatment-related hospitalisation (8.5% versus 13.2%; $p=0.048$). However, the analysis did not confirm non-inferiority of ctDNA-guided treatment de-escalation, and the 3-year recurrence-free survival was 85.3% versus 88.1% (97.5% lower CI: −8.0%). The pre-planned subgroup analysis suggested de-escalation may be non-inferior in clinical low-risk tumours (T1-3N1), with a 3-year recurrence-free survival of 91.0% versus 93.2% (97.5% lower CI: −7.2%).

In summary, the results of the DYNAMIC-III study suggest that ctDNA-guided de-escalation is feasible and reduces oxaliplatin exposure and adverse events, with outcomes approaching standard management. Benefit may be seen, particularly for patients with low-risk tumours, but further research is needed to confirm this.

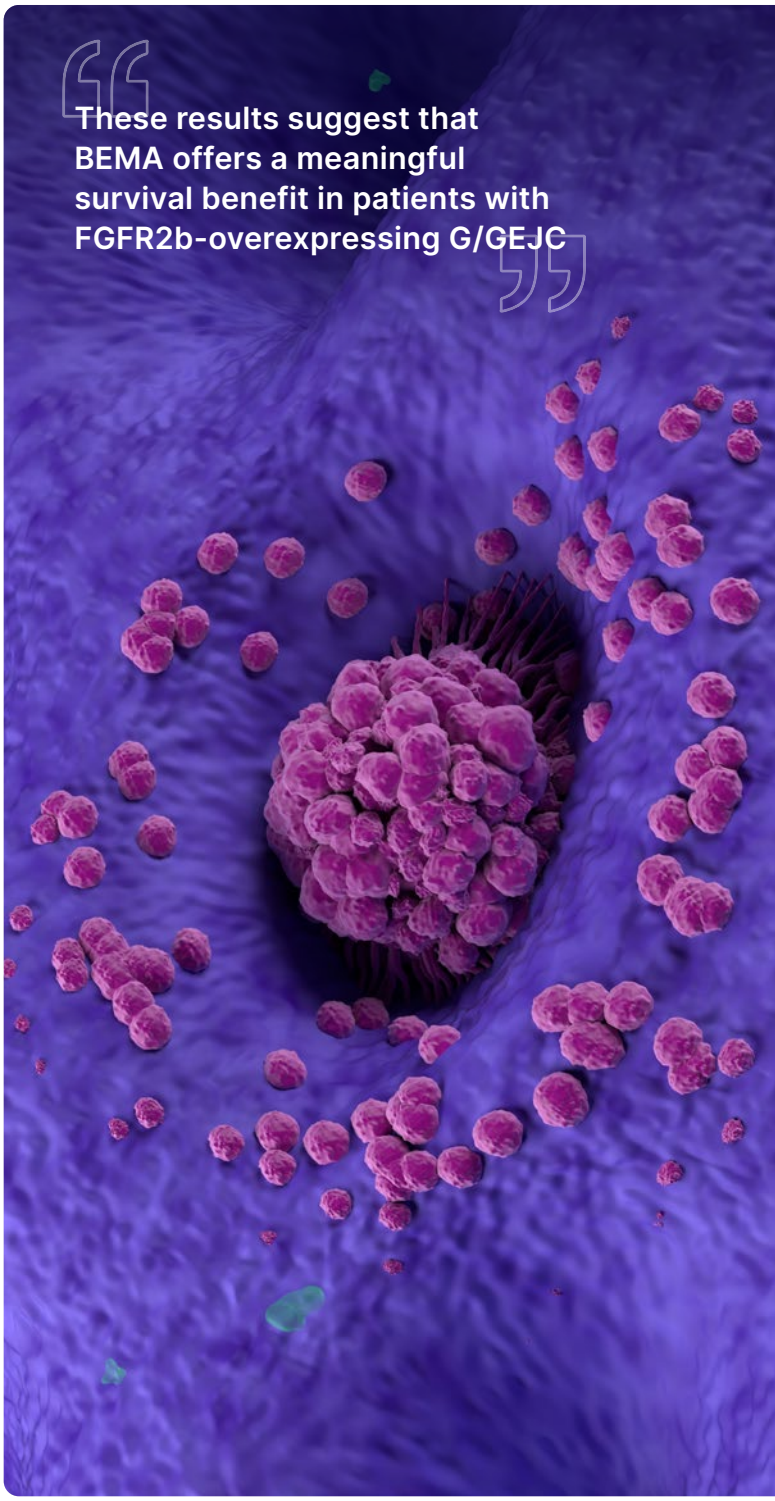
Bemarituzumab Significantly Improves Survival in Gastric Cancer

A RECENT Phase III trial, presented at the ESMO 2025 Congress, has demonstrated that bemarituzumab (BEMA), a first-in-class anti-FGFR2b antibody, significantly improves overall survival (OS) in patients with FGFR2b-overexpressing, non-HER2-positive, unresectable, locally advanced or metastatic gastric or gastro-oesophageal junction cancer (G/GEJC).[9]

BEMA functions by blocking oncogenic FGFR2b signalling and engaging antibody-dependent cell-mediated cytotoxicity. In this study, 547 patients were randomised to receive BEMA plus mFOLFOX6 or a matched placebo plus mFOLFOX6, with primary analysis focused on those with FGFR2b ≥10% tumour cell staining. Key secondary endpoints included progression-free survival, objective response rate, and safety.

At the primary analysis, with a median follow-up of 11.8 months, BEMA significantly improved OS compared with placebo, with a median OS of 17.9 months versus 12.5 months and a hazard ratio of 0.61 (95% CI: 0.43–0.86; p=0.005). In the descriptive follow-up analysis, at a median follow-up of 19.4 months, the median OS remained numerically higher with BEMA (14.5 versus 13.2 months), although the treatment effect was attenuated (hazard ratio: 0.82; 95% CI: 0.62–1.08). The safety profile was consistent with expectations, with higher rates of Grade ≥3 treatment-emergent adverse events observed in the BEMA arm, primarily driven by corneal events.

These results suggest that BEMA offers a meaningful survival benefit in patients with FGFR2b-overexpressing G/GEJC, particularly in those with ≥10% tumour cell staining. While the effect was somewhat reduced with longer follow-up, the initial findings support the potential of BEMA as a new targeted therapy in this setting. Further studies, including the upcoming FORTITUDE-102 trial, will help to better define the long-term efficacy and safety of BEMA, offering hope for improved outcomes in this difficult-to-treat patient population.



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