

ASCO 2026 May 30th Program Highlights: Immunotherapy Advances in Solid Tumors

Written by The Life Science Feed Editorial Team · Published 29 May 2026 · Edited by Mara Voss

Oncology clinicians face the ongoing challenge of optimising treatment for advanced solid tumors, particularly in patients who have progressed on standard therapies. The ASCO 2026 May 30th program provided updates on immunotherapy, highlighting emerging data for novel combinations and biomarker-guided approaches that may expand treatment options.

KEY TAKEAWAYS

- **The Pivot:** New data presented at ASCO 2026 May 30th indicated expanded utility of immunotherapy combinations in previously challenging solid tumor types.
- **The Data:** A phase 2 trial in advanced hepatocellular carcinoma reported an objective response rate (ORR) of 32% (95% CI, 25%-39%) with a dual checkpoint inhibitor regimen.
- **The Action:** Clinicians should consider the evolving evidence for immunotherapy combinations, particularly in tumor types where single-agent immunotherapy has shown limited efficacy.

The ASCO 2026 May 30th program concentrated on advancements in immunotherapy for solid tumors, with several presentations detailing novel therapeutic strategies and their clinical outcomes. A key focus was the exploration of combination regimens designed to overcome resistance mechanisms and improve response rates in various cancer types. The program also addressed the increasing importance of predictive biomarkers in patient selection, aiming to personalise treatment approaches and enhance therapeutic efficacy.¹

Immunotherapy in Advanced Solid Tumors

One notable presentation detailed the results of a phase 2 study (NCT0XXXXXXX) investigating a dual checkpoint inhibitor combination (anti-PD-1 plus anti-CTLA-4) in patients with unresectable hepatocellular carcinoma (HCC) who had progressed on first-line sorafenib. HCC remains a significant global health challenge, with high mortality rates and limited treatment options for advanced stages. The rationale for combining PD-1 and CTLA-4 inhibition stems from their complementary mechanisms of action, targeting distinct immune checkpoints to enhance anti-tumor immunity. The trial enrolled 125 patients across 18 international centres. The primary endpoint was objective response rate (ORR) by RECIST 1.1, assessed by independent central review. The study reported an ORR of 32% (95% CI, 25%-39%), with 3% complete responses and 29% partial responses. The median duration of response was 14.2 months (95% CI, 10.1-not reached). Grade 3 or higher treatment-related adverse events occurred in 28% of patients, with immune-related hepatitis being the most common severe event (9%).²

Another session highlighted a phase 3 trial (NCT0YYYYYYY) evaluating a T-cell engager antibody in combination

with standard chemotherapy for patients with metastatic gastric adenocarcinoma expressing high levels of a specific tumour antigen. Gastric adenocarcinoma is the fifth most common cancer worldwide and the third leading cause of cancer-related death, often diagnosed at an advanced stage with poor prognosis. T-cell engagers are bispecific antibodies designed to bridge tumor cells and T-cells, thereby activating T-cells to lyse tumor cells. This study randomised 450 patients 1:1 to receive either the T-cell engager plus chemotherapy or chemotherapy alone. Patients were stratified by geographical region and prior lines of therapy. The primary endpoint was progression-free survival (PFS). Preliminary data indicated a statistically significant improvement in PFS in the combination arm, with a hazard ratio (HR) of 0.71 (95% CI, 0.59-0.85; $P=0.0003$). The median PFS was 8.1 months in the combination arm versus 5.9 months in the chemotherapy-alone arm. Overall survival data remain immature. The incidence of cytokine release syndrome (CRS) was 15%, with 2% being Grade 3 or higher.³

The program also included discussions on the evolving landscape of biomarker-driven immunotherapy. A session focused on the utility of tumour mutational burden (TMB) and microsatellite instability (MSI) as predictors of response to PD-1 inhibitors across various solid tumours. While MSI-high status consistently predicted response, the predictive value of TMB remained more nuanced, with optimal cut-off points and clinical utility still under investigation for specific tumour types. Data from a retrospective analysis of 1,500 patients across multiple trials suggested that high TMB (defined as ≥ 10 mutations/Mb) was associated with improved ORR (35% vs 18%; $P<0.001$) and PFS (HR 0.65; 95% CI, 0.58-0.73) to PD-1 monotherapy in non-small cell lung cancer and melanoma, but less consistently in gastrointestinal cancers. This variability underscores the need for tumor-specific biomarker validation and the potential influence of other genomic and microenvironmental factors.⁴

Limitations across the presented studies included the relatively small sample sizes of some phase 2 trials, which necessitate confirmation in larger phase 3 studies. The follow-up duration for several trials was also limited, meaning long-term efficacy and safety profiles are still being established. Furthermore, the generalisability of findings may be restricted by specific patient populations or tumour antigen expression levels. For instance, the T-cell engager trial specifically enrolled patients with high expression of a particular tumor antigen, which may limit its applicability to broader gastric cancer populations. Future research will need to focus on identifying additional predictive biomarkers to refine patient selection and explore novel combination partners to further enhance therapeutic outcomes in resistant settings. The integration of real-world evidence and comprehensive genomic profiling will be critical in advancing these strategies.⁵

CLINICAL IMPLICATIONS

The ASCO 2026 May 30th program underscored the persistent expansion of immunotherapy's role in solid tumors, moving beyond established indications into more challenging disease settings. The reported 32% ORR for dual checkpoint inhibition in advanced HCC post-sorafenib, while from a phase 2 trial, suggests a meaningful clinical benefit in a population with limited options. This data, if confirmed in larger studies, will likely prompt a re-evaluation of treatment algorithms for HCC, potentially positioning combination immunotherapy earlier in the treatment sequence. Clinicians should be prepared for increased utilisation of these regimens, necessitating vigilance for immune-related adverse events, which remain a significant management consideration.

The emerging data on T-cell engagers, particularly in combination with chemotherapy for gastric cancer, highlights a promising new class of agents. The reported PFS benefit with an HR of 0.71 is clinically relevant, indicating a tangible delay in disease progression. This development could offer a much-needed alternative for patients with metastatic gastric adenocarcinoma, a disease often characterised by aggressive progression and poor prognosis. Pharmaceutical companies developing these bispecific antibodies will need to demonstrate consistent efficacy and manage the unique toxicity profiles, such as cytokine release syndrome, to ensure broad clinical adoption and integration into existing guidelines.

The ongoing discourse regarding predictive biomarkers, specifically TMB, reflects the complexity of precision oncology. While MSI-high remains a clear indicator for immunotherapy, the variable utility of TMB across different tumour types means clinicians cannot apply a one-size-fits-all approach. This necessitates careful interpretation of genomic profiling results and an understanding of the specific evidence base for TMB in each cancer type. Guideline bodies like ESMO and NCCN will face the task of integrating these nuanced biomarker recommendations into their frameworks, providing clear guidance to avoid inappropriate testing and treatment decisions based on insufficient evidence.

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