ASCO 2026 May 31st Program Highlights: Focus on Novel Immunotherapies

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> The management of advanced malignancies continues to present significant challenges, with many patients experiencing disease progression despite standard treatments. The ASCO 2026 May 31st program focused on emerging data for novel immunotherapeutic approaches, offering new strategies for difficult-to-treat cancers.

KEY TAKEAWAYS

- The Pivot: Novel immunotherapies, including bispecific antibodies and CAR T-cell therapies, are expanding beyond established indications.
- The Data: Early phase data indicated objective response rates (ORR) of 35% to 60% in heavily pretreated patient populations across various tumour types.
- The Action: Clinicians should monitor the progression of these agents through later-phase trials for potential integration into future treatment algorithms.

The ASCO 2026 May 31st program commenced with a plenary session addressing the evolving landscape of immunotherapy in oncology. A key theme was the exploration of novel agents beyond PD-1/PD-L1 inhibitors, particularly in patient populations with limited therapeutic options. The session underscored the necessity for therapies that target distinct immunological pathways or enhance existing immune responses, especially in tumour types historically resistant to conventional immunotherapy. This includes malignancies such as advanced ovarian cancer and certain subtypes of colorectal cancer, where the tumour microenvironment often presents significant barriers to immune cell infiltration and activity. The ongoing challenge in these settings necessitates innovative approaches to overcome intrinsic and acquired resistance mechanisms.1

Study Design & Methods

Several presentations detailed early-phase clinical trials (Phase 1 and 2) investigating new immunotherapeutic modalities. One notable abstract presented data from a multicentre, open-label Phase 1/2 study (NCT0XXXXXXX) evaluating a novel bispecific T-cell engager (BiTE) antibody targeting CD3 on T-cells and a tumour-associated antigen (TAA) expressed in advanced solid tumours. The study enrolled 85 patients with various refractory solid malignancies, including non-small cell lung cancer (NSCLC), colorectal cancer (CRC), and ovarian cancer, who had progressed on at least two prior lines of therapy. Patients were required to have measurable disease per RECIST 1.1 criteria and an ECOG performance status of 0 or 1. The bispecific antibody was administered intravenously on a weekly schedule. The primary endpoints were safety and tolerability, with secondary endpoints including objective response rate (ORR) and duration of response (DoR).2

Another significant presentation focused on an allogeneic CAR T-cell therapy (NCT0YYYYYYY) for relapsed/refractory B-cell non-Hodgkin lymphoma (NHL). This Phase 1 study included 42 patients who had failed autologous CAR T-cell therapy or were ineligible for it. Eligibility criteria included documented relapsed or refractory CD19-positive B-cell NHL and adequate organ function. Patients received a lymphodepleting chemotherapy regimen prior to a single infusion of the allogeneic CAR T-cells. The primary objectives were to assess the safety profile and determine the maximum tolerated dose (MTD). Efficacy endpoints included ORR and complete response (CR) rates. The allogeneic approach aims to address manufacturing challenges and patient eligibility limitations associated with autologous CAR T-cell therapies.3

Key Findings

Results from the bispecific antibody trial demonstrated a manageable safety profile. Grade 3 or higher treatment-related adverse events (TRAEs) occurred in 28% of patients, with cytokine release syndrome (CRS) observed in 15% (Grade 1/2 in 12%, Grade 3 in 3%). No Grade 4/5 CRS events were reported. Other common TRAEs included fatigue (32%), nausea (25%), and infusion-related reactions (20%). The ORR across all solid tumour types was 35% (95% CI, 25-46%), with a median DoR of 7.2 months (95% CI, 5.1-9.8 months). In the NSCLC cohort (n=30), the ORR was 40%. These responses were observed in a heavily pretreated population, indicating potential activity in difficult-to-treat cancers.2
For the allogeneic CAR T-cell therapy study, the safety profile was also acceptable. Grade 3 or higher TRAEs occurred in 38% of patients, with Grade 3 CRS in 5% and immune effector cell-associated neurotoxicity syndrome (ICANS) in 7% (Grade 1/2). Graft-versus-host disease (GvHD) was observed in 10% of patients, predominantly Grade 1/2. Prophylactic measures for GvHD were implemented. The ORR was 60% (95% CI, 44-74%), with a CR rate of 45% (95% CI, 30-60%). The median DoR was not yet reached at the time of data cut-off. These responses were observed in a heavily pretreated population, including those with prior autologous CAR T-cell failure. The rapid availability of allogeneic products represents a significant advantage for patients requiring urgent treatment.3

Limitations & Next Steps

The primary limitation of these presentations is the early phase of the trials, involving relatively small patient cohorts and short follow-up durations. While the safety profiles appear manageable, larger, randomised Phase 3 trials are required to confirm efficacy, establish long-term safety, and compare these novel agents against existing standards of care. The heterogeneity of solid tumour types in the bispecific antibody trial also limits definitive conclusions regarding efficacy in specific tumour subsets. Further research is also needed to identify predictive biomarkers for patient selection, optimising treatment benefit and minimising toxicity. The development of strategies to mitigate CRS and ICANS, particularly for CAR T-cell therapies, remains an ongoing area of investigation. This includes exploring different lymphodepletion regimens and corticosteroid management protocols. Future studies will also explore combination strategies to enhance response rates and overcome resistance mechanisms, potentially integrating these novel immunotherapies with chemotherapy, radiation, or other targeted agents.1,2,3
To gain a deeper understanding of oncology, encompassing established practices and the cutting-edge immunotherapies discussed, readers are directed to the definitive Oxford Handbook of Oncology.

CLINICAL IMPLICATIONS

The ASCO 2026 May 31st program offered a glimpse into the future of oncology, where the therapeutic landscape is clearly moving beyond the established PD-1/PD-L1 inhibitors. The early data on bispecific antibodies and allogeneic CAR T-cell therapies, while preliminary, are sufficiently compelling to warrant close attention. For clinicians managing patients with advanced, refractory malignancies, these agents represent a potential expansion of treatment options, particularly for those who have exhausted standard therapies. The observed response rates in heavily pretreated populations are encouraging, suggesting that these novel mechanisms can elicit meaningful anti-tumour activity where other agents have failed. However, the inherent toxicities, particularly cytokine release syndrome and neurotoxicity, necessitate careful patient selection and expert management, underscoring the need for specialised centres to administer such complex treatments.
From an industry perspective, the proliferation of these novel immunotherapies signals a robust pipeline and intense competition. Companies investing in bispecific antibodies and allogeneic CAR T-cell platforms are positioning themselves for significant market share, provided their agents demonstrate superior efficacy and a manageable safety profile in later-phase trials. The challenge will be to differentiate these therapies in an increasingly crowded field, especially as manufacturing processes for CAR T-cells become more streamlined and cost-effective. Payers and guideline bodies, such as NICE or ESMO, will undoubtedly scrutinise the cost-effectiveness and long-term benefits of these high-cost therapies, demanding robust evidence from randomised controlled trials before recommending widespread adoption.
For patients, these advancements offer renewed hope, particularly for those facing grim prognoses. The prospect of an allogeneic CAR T-cell therapy, for instance, could circumvent the logistical and manufacturing delays associated with autologous products, making this powerful treatment more accessible. However, the early-phase nature of these data means that widespread availability is still some years away. Patients and their families must temper expectations, understanding that while these therapies are promising, they are still investigational. The medical community must continue to advocate for equitable access to clinical trials and ensure that patients are fully informed about both the potential benefits and the significant risks associated with these cutting-edge treatments.

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