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# The ADC Pendulum: Following the Arc from Approval to Withdrawal and Renewed Promise

## Former FDA experts reflect on 25 years of ADC therapies and key insights for ADC development

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## Executive Summary

Antibody–drug conjugates (ADCs) have helped transform cancer therapy over the last 25 years, with 15 ADCs approved by FDA to date.[1] By linking targeted antibodies with cytotoxic payloads, ADCs deliver precision chemotherapy with the aim of potent efficacy while limiting toxicity. While some ADCs have yielded practice-changing results, others have encountered insurmountable challenges. By 2023, roughly a third of ADC trials had been discontinued, often due to poor efficacy at tolerable doses.[2,3]

This whitepaper reviews three ADCs – gemtuzumab ozogamicin (GO), belantamab mafodotin, and sacituzumab govitecan – each achieving an initial accelerated approval but were later withdrawn, with two removed from the market entirely. Together, these ADCs highlight recurring pitfalls in dose selection, toxicity management, and the predictability of early endpoints, offering clear lessons for sponsors developing the next generation of ADCs.

## Introduction

Antibody–drug conjugates (ADCs) have reshaped the field of oncology over the past quarter century. By linking a monoclonal antibody to a cytotoxic payload, ADCs enable the targeted delivery of chemotherapy agents, improving efficacy while minimizing off-target effects. Since the first FDA approval of an ADC 25 years ago, the field of ADCs has expanded rapidly. To date, 15 ADCs have been approved in the United States for the treatment of hematologic and solid tumors, with many more in development. Numerous ADC therapies have realized their therapeutic potential while leveraging FDA expedited programs (e.g., breakthrough therapy, priority review, accelerated approval); however, several barriers have prevented the successful development of other ADCs. In 2023, an estimated 35% of ADC candidates (92 of 260) had been discontinued following clinical trials, often because efficacy could not be demonstrated at tolerable doses.[2,3] Such barriers are particularly acute for the next generation of oncology ADCs, which are becoming increasingly complex. Thus, it is important to examine and understand the factors that have led to stalled or withdrawal of certain ADC drugs or indications, to help guide more successful development in the future.

This white paper outlines key learnings from three ADC products – gemtuzumab ozogamicin (GO), belantamab mafodotin, and sacituzumab govitecan – each granted accelerated approval but subsequent clinical trial data failed to verify clinical benefit and resulted in withdrawal of either the asset or the indication.

By examining these case studies and drawing on nearly 20 years of combined FDA experience, we provide regulatory insight into the recurring pitfalls in dose selection, toxicity management, the impact of trial population(s), and trial design — affording opportunity for sponsors to augment their own ADC development programs.

A companion paper, also from the Institute@Precision, explores ADCs that have successfully navigated these hurdles to deliver practice-changing results in the frontline treatment setting. Together, the two papers capture the arc of the ADC pendulum — from early promise to paradigm shifting success through setbacks with some leading to withdrawal — offering developers a balanced view of the risks that can derail programs, and the strategies that can lead to a higher probability of technical and regulatory success.

## Gemtuzumab Ozogamicin: The Pioneer and the Comeback

**(Mylotarg™, Pfizer/Wyeth-Ayerst Laboratories)**

The initial ADC, gemtuzumab ozogamicin (GO), linking a humanized anti-CD33 antibody (expressed on AML blasts) to ozogamicin, a calicheamicin derivative, was granted accelerated approval in 2000 for patients with CD33 positive AML in first relapse who were 60 years of age or older and were not candidates for cytotoxic chemotherapy.

This was supported by phase 2 single-arm studies in 142 patients, which showed a complete response rate (CR) of 16% (95% CI: 11, 23) and an overall response rate (ORR) of 30% (95% CI: 22, 38) with durability.[4] The initial dosage approved was 9 mg/kg based on CD33 target saturation and clinical data. In the post market setting, fatal events of hepatotoxicity and veno-occlusive disease (VOD) occurred, leading to a labeled boxed warning. The risk of fatal and severe hepatotoxicity and VOD was not realized with the initial safety data from single-arm trials.

The confirmatory trial for GO, SWOG-0106, a Phase III trial evaluating GO at 6 mg/kg in combination with induction therapy in patients ≤60 years of age with newly diagnosed AML, failed to demonstrate benefit across efficacy endpoints, including CR, disease-free survival, and overall survival (OS).[5,6] Following these results, Pfizer, in consultation with FDA, voluntarily withdrew GO from the US market in 2010.[5,6]

### The Comeback

The initial accelerated approval of GO was at a dosage of 9 mg/kg and, notably, the confirmatory SWOG-0106 trial evaluated a lower dose of 6 mg/kg in combination. The risk of severe and fatal hepatotoxicity and VOD occurred at both doses. Following the voluntary withdrawal from the market, additional PK analyses were conducted to further characterize the risk of severe and fatal hepatotoxicity. The additional analyses identified that exposure, as measured by Cmax and AUC, was exponential, even with small increases in dose. The exposure relationship clearly underpinned the incidence and severity of hepatotoxicity at the original 9 mg/kg dose and in the frontline confirmatory trial at a dose of 6 mg/kg. This was coupled with a flat exposure-response relationship for efficacy. Thus, lower fractionated doses were evaluated to offset the toxicity risk leading to subsequent clinical trials, Mylofrance 1 and ALFA-701. Mylofrance 1 evaluated GO at 3 mg/kg on days 1, 4, and 7 of induction in patients with AML in first relapse.[7] The trial demonstrated a CR rate of 26% (95% CI: 16%, 40%) and a median relapse-free survival of 11.6 months.[8] This was further bolstered by the ALFA-701 trial, a randomized trial also evaluating the 3 mg/kg dose on days 1, 4, and 7 in patients 50-70 years with newly diagnosed AML. The trial demonstrated a statistically significant improvement in event-free survival (HR 0.56, 95% CI: 0.42, 0.76). The ALFA-701 trial still showed a risk of severe or fatal hepatotoxicity/VOD.[9] A subsequent marketing application was submitted in November 2016 and was discussed at FDA's Oncologic Drugs Advisory Committee (ODAC) meeting in July 2017 and ultimately granted traditional approval in September 2017.

**The development of GO for AML represents the pioneering journey in ADC development culminating in several key lessons:**

**Target expression drove toxicity** – CD33, while highly expressed on AML blasts, is also expressed on sinusoidal endothelial cells and hepatocytes, leading to hepatic microvascular damage and the development of VOD. This highlights the potent targeting capabilities of ADCs. Notably, for GO, the hepatotoxicity and VOD was not realized with the initial single arm data despite the target-mediated toxicity effect.

**PK & exposure-response relationship** – It is imperative to develop a comprehensive understanding of the PK of the antibody and the payload, along with linker considerations. For GO, the initial PK data at 9 mg/kg and 6 mg/kg yielded an accumulation of GO across multiple doses, corresponding increases in Cmax and AUC, and corresponding decreases in clearance and volume of distribution. Additionally, there was a dearth of data at lower doses and population PK modeling was leveraged to simulate the PK at lower doses. The model ultimately didn't correlate with the available clinical data and underpredicted exposure. The variability and uncertainty limited the ability to fully characterize PK and the exposure response relationships, leading to inadequate dose selection as monotherapy and in combination in the initial clinical trials.

"Gemtuzumab ozogamicin was a milestone as the first approved ADC. However, a high single-dose regimen proved unsustainable. What made this case unusual was that the hepatotoxicity signal first emerged in the post-marketing setting, not during clinical development. The confirmatory trial then reinforced concerns, showing that even at a lower dose, toxicity undermined the drug's benefit. It was an early but important lesson in how critical dosing strategy is to long-term success."

– Nicholas Richardson, VP Clinical Development, Precision for Medicine

## Belantamab Mafodotin: When Toxicity Trumps Efficacy

**(Blenrep®, GSK)**

Belantamab mafodotin is an ADC targeting B-cell maturation antigen (BCMA), expressed on malignant plasma cells in multiple myeloma, and conjugated to the cytotoxic payload monomethyl auristatin F (MMAF), a microtubule inhibitor.[9] In 2020, belantamab mafodotin was granted accelerated approval for patients with relapsed or refractory multiple myeloma (RRMM) who have received four or more prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.[10] The approval was based on the DREAMM-2 trial with an ORR of 31% (95% CI: 21, 43) with durability at the recommended dose of 2.5 mg/kg every 3 weeks.[10]

The key risk with belantamab mafodotin is ocular toxicity, including keratopathy (changes in the corneal epithelium) and vision changes. This results from belantamab mafodotin being delivered to corneal epithelial cells likely via soluble BCMA, which sheds from myeloma cells and is present in blood and tears. In the DREAMM-2 trial, any grade ocular adverse events (AEs) occurred in 71%, with Grade ≥3 ocular AEs in 44% of patients.[11] This was associated with dose interruptions in 47%, dose reductions in 23%, and treatment discontinuation in 2%. Dose interruption is the primary modality to manage ocular toxicity with belantamab mafodotin. Because of the ocular toxicity and its impact, the initial marketing application was discussed at an ODAC in 2020, with a unanimous vote that the benefits outweighed the risks in a heavily pre-treated population with appropriate mitigation strategies in place (i.e., REMS).

With the accelerated approval, DREAMM-3 was considered the confirmatory trial, which was an add-on design evaluating belantamab mafodotin (2.5 mg/kg) with pomalidomide and dexamethasone. The trial results showed no significant improvement in the primary endpoint of progression-free survival (PFS), and importantly, a potential detriment in OS. Thus, GSK voluntarily withdrew belantamab mafodotin from the US market in 2022, in consultation with FDA.[12] Although, GSK had developed a robust portfolio of randomized trials evaluating belantamab that remained ongoing, including the DREAMM-7 and -8 trials in an earlier treatment setting.[13]

### The Toxicity Conundrum

The DREAMM-7 and -8 randomized trials evaluated belantamab mafodotin (DREAMM-7: 2.5 mg/kg every 3 weeks; DREAMM-8: 2.5 mg/kg Cycle 1, 1.9 mg/kg Cycle 2+), in triplet combinations in patients with multiple myeloma (MM) in the second line setting and beyond. Both trials demonstrated a statistically significant PFS advantage (DREAMM-7 PFS HR: 0.41, 95% CI: 0.31, 0.53; DREAMM-8 PFS HR: 0.52, 95% CI: 0.37, 0.73) and DREAMM-7 also demonstrated a statistically significant advantage in OS (OS HR: 0.58, 95% CI: 0.43, 0.79). The efficacy results were coupled with high rates of ocular toxicity in both DREAMM-7 and DREAM-8: any grade 92%, 93%; Grade 3-4 77%, 78%; dose interruption 74%, 75%; dose reduction 30%, 57%; and discontinuation 6%, 7%, respectively. Because of the toxicity and tolerability concerns, the DREAMM-7 and -8 trials were discussed at the July 2025 ODAC, with a negative vote regarding the benefit-risk of belantamab mafodotin. The ODAC cited their rationale as the proposed dosing regimens with unacceptable ocular toxicity and poor tolerability.[14]

The development of belantamab mafodotin has been arduous and exemplifies the impact of clinically significant toxicity in the presence of notable efficacy across lines of therapy. Visual toxicity is paramount, with a potenail for limited ability to read, drive, or navigate ones surroundings. There is a need for balance and understanding of such toxicity in the setting of clinically meaningful efficacy.

Belantamab mafodotin was granted breakthrough therapy designation in 2017 by FDA, clearly denoting its potential. However, at that time, it was noted by FDA that further dose evaluation and optimization was needed given the ocular toxicity and its impact on tolerability. The selected approach of concurrently evaluating different dosages and frequencies while conducting registrational trials with iterations of the originally approved dose led to the more recent second ODAC. Here we saw an unfavorable vote despite clinically meaningful efficacy, including an overall survival benefit in DREAMM-7. In the wake of this vote, FDA approved belantamab in combination with bortezomib and dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and immunomodulatory agent. This was a more refractory population than studied in the DREAM-7 trial, suggesting the benefit may only outweigh the risks in later stages.

Based on the belantamab mafodotin data suggesting dose interruption is the ideal management for ocular toxicity, longer duration between doses may improve toxicity and tolerability. This concept is being evaluated in the ongoing DREAMM-10 trial in patients with newly diagnosed transplant-ineligible MM, who are being treated at a lower dose of at 1.9 mg/kg with less frequent dosing.

## Sacituzumab Govitecan: The Quandary of Patient Selection

**(Trodelvy®, Gilead Sciences)**

Sacituzumab govitecan, an ADC composed of an anti-Trop-2 antibody linked to SN-38, the active metabolite of irinotecan. Trop-2 is expressed in multiple epithelial cancers, including breast and urothelial cancers. In 2021, sacituzumab govitecan received accelerated approval for the treatment of patients with locally advanced or metastatic urothelial cancer (mUC) following platinum-based chemotherapy and PD-1/PD-L1 inhibitors.[15] The approval was based on a Phase II single-arm trial, TROPHY-U-01, with an ORR of 28% (95% CI: 20, 37), including a 5% CR with durability. The initial dosage approved was 10 mg/kg IV on days 1 and 8 of a 21-day cycle.[16]

The confirmatory TROPiCS-04 Phase III trial evaluated sacituzumab govitecan monotherapy at the 10 mg/kg dose in the same population as the AA indication and failed to meet its primary OS endpoint (HR: 0.86, 95% CI: 0.73, 1.02). Notably, a higher fatal adverse event rate at 7% of patients in the sacituzumab govitecan arm (vs. 2% with chemotherapy) along with Grade ≥3 adverse events at 77% (51% with chemotherapy), primarily due to neutropenia, febrile neutropenia, and infections, contributed to missed endpoint. Faced with this data, Gilead voluntarily withdrew the urothelial cancer indication in consultation with FDA in 2024.[15]

Similar to GO in AML and the risk of hepatotoxicity, the risk of neutropenia and infections with sacituzumab govitecan was not fully elucidated based on the single-arm trial data. A likely contributor was patient selection across the initial single-arm trial and the randomized trial, both in the same urothelial cancer population. In the TROPiCS-04 trial, patients at an increased risk of fatal or serious adverse events were older adults (>65 years of age), heavily pretreated, and had a prior cystectomy or prior urinary tract procedure. When evaluating these characteristics across the single-arm TROPHY-U-01 trial versus the TROPiCS-04 trial, the median age was similar, although a higher proportion of patients, 37% (vs 23%), were ≥75 years in TROPiCS-04. Yet, patients in TROPiCS-04 were less heavily pretreated with 70% with 1-2 prior therapies, versus 47%. In either trial, additional mitigation strategies for neutropenia, such as primary granulocyte-colony stimulating factor (G-CSF) prophylaxis, were not included.

"In my time at FDA, I had many conversations with developers on dose selection and the legitimate concern with lowering the dose and potentially compromising efficacy. But chasing maximum efficacy can lead to compromising both long term benefit and safety. FDA expects dose optimization to be central in ADC development."

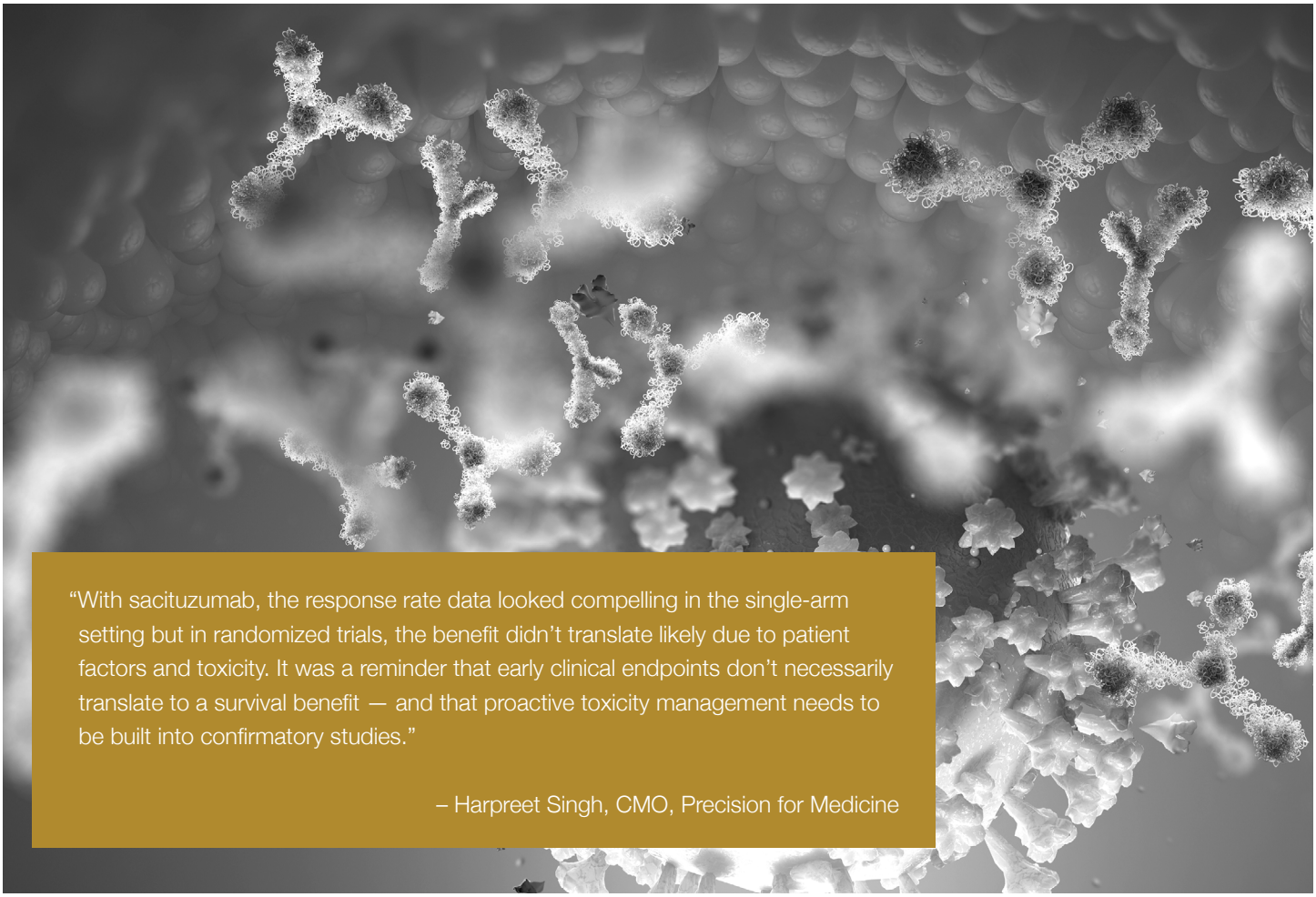
– Nicholas Richardson, VP Clinical Development, Precision for Medicine

The development of sacituzumab govitecan in urothelial cancer highlights the potential uncertainty with single-arm trial efficacy and safety data. Regarding efficacy, response rate data suggested benefit, but did not translate in a broader population evaluated for long-term outcomes of OS and PFS. Unlike ORR, an OS endpoint in the setting of a randomized trial incorporates the natural history of the disease, subsequent therapies, and the drug's safety profile relative to the comparator.

**The development of sacituzumab has demonstrated benefit in locally advanced or metastatic breast cancer, but in urothelial cancer, some key lessons occurred:**

**Trial population shapes outcomes** – Although the 2 trials were in the same population, differences in patient characteristics across the trials may have led to more pronounced toxicity in the RCT. A descriptive comparison of patient characteristics didn't identify a unified explanation for the increased rates of neutropenia and infection in the TROPiCS-04 trial, highlighting the limitations of cross-trial comparisons. Yet, the occurrence of fatal infectious events contributed to the OS results. There are underlying biases in patient selection for a single-arm trial with an investigational product versus a RCT with a SOC comparator arm, which may have played a substantial role with sacituzimab in UC.

**Supportive care enables tolerability** – Appropriate toxicity management (such as prophylactic G-CSF) to mitigate neutropenia, may have improved tolerability and outcomes. The single-arm data with sacituzimab didn't meet the ASCO Clinical Practice Guidelines threshold of ≥20% febrile neutropenia (TROPHY-U-01 febrile neutropenia incidence 10%) supporting use of prophylactic G-CSF. Although, the intended patient population includes patients who are at high risk for neutropenia based on age, medical history, disease characteristics, and prior therapies. Proactive planning and implementing toxicity management strategies based on emerging data in the context of the disease and treatment setting are crucial.



"With sacituzumab, the response rate data looked compelling in the single-arm setting but in randomized trials, the benefit didn't translate likely due to patient factors and toxicity. It was a reminder that early clinical endpoints don't necessarily translate to a survival benefit — and that proactive toxicity management needs to be built into confirmatory studies."

– Harpreet Singh, CMO, Precision for Medicine

## Strategic Insights for ADC Sponsors

**The three case studies illustrate regulatory precedents that offer key principles in the development and evaluation of next-generation ADCs.**

### 1. Early investment in dosage and regimen

A key question following early phase ADC data is whether there is a comprehensive understanding of the PK for the antibody and the payload, the contribution of the linker, and how that impacts the exposure-response for efficacy and safety. This is coupled with generating sufficient clinical data across dose levels for safety and preliminary efficacy. The pioneer ADC gemtuzumab is a clear case of these principles and how it can impact a clinical development timeline, including a 7-year gap between the initial accelerated approval and conversion to a traditional approval. This was attributed to further evaluation of PK and exposure-response data, allowing for an efficacious and tolerable regimen, both in monotherapy and in combination. Notably, this timeline would not be accepted today following the passage of the Consolidation Appropriations Act in 2023, providing FDA authority to require that a confirmatory study or studies be underway prior to an accelerated approval.[17] The median time from accelerated approval to verification of clinical benefit is approximately 3 years for oncology indications.[9] Thus, ADC development and the ability to achieve regulatory and technical success hinges on adequate early evaluation regarding dose and regimen in support of proceeding to registrational studies.

### 2. Proactive toxicity management

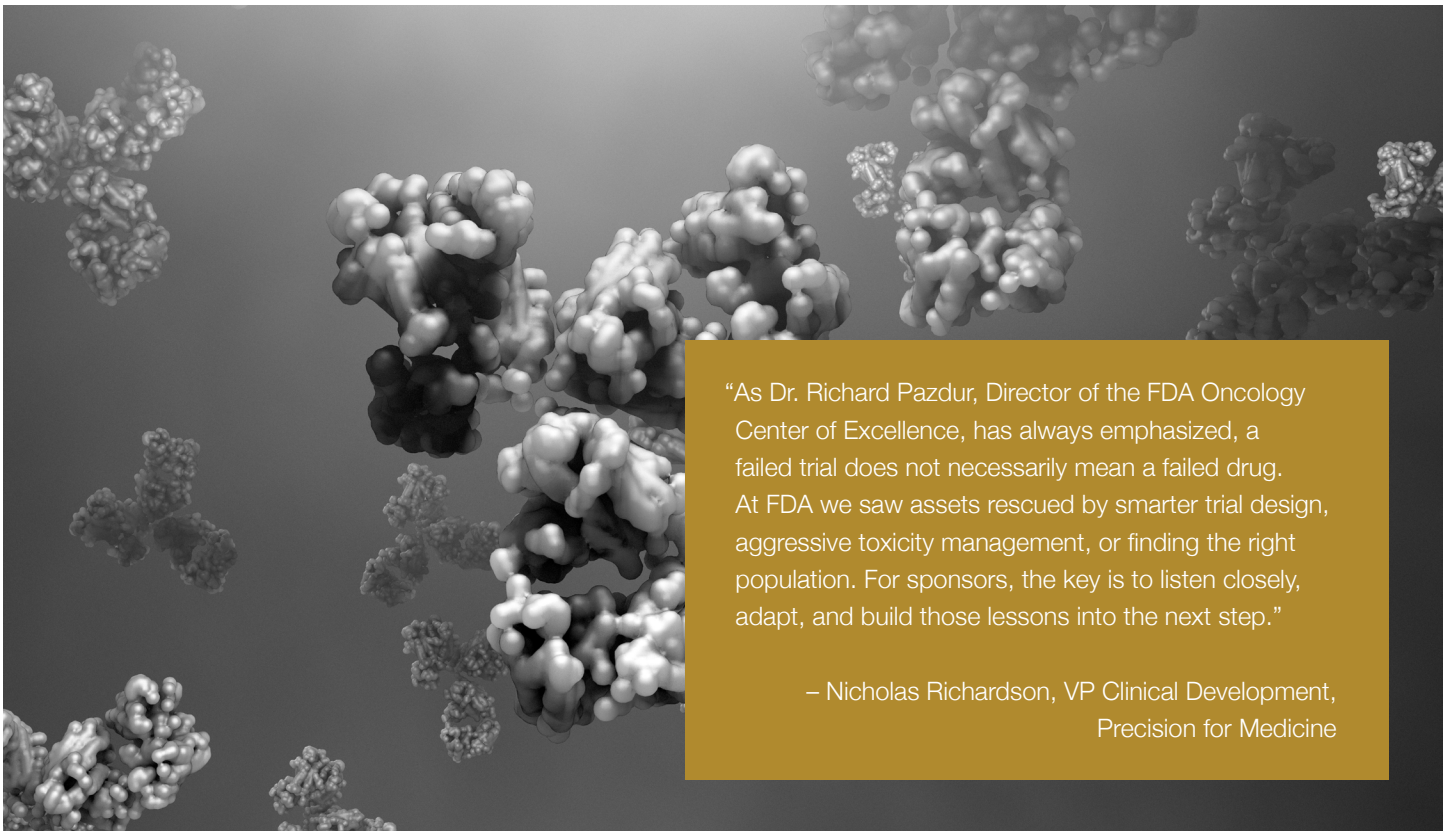
Numerous ADCs have unique and potential dose limiting toxicities associated with the target or the payload. The 3 case studies each demonstrate clinically significant toxicities (hepatotoxicity and VOD, ocular toxicity, and neutropenia and severe infections). FDA and Sponsors expect early phase clinical data to establish the toxicity risk along with appropriate mitigation strategies. Evaluating differences in toxicity risk across dose levels and treatment schedule, implementing standardized mitigation, and adjusting based on emerging data is necessary to further development. For instance, in the early phase trials with belantamab, a sub study was conducted to assess aggressive implementation of corticosteroid eye drops and prophylactic tears, resulting in evidence that eye drops do not mitigate the ocular toxicity and that dose interruptions are the main modality to manage ocular toxicity. This finding directly impacted the dose schedule considerations for belantamab. In contrast, the sacituzumab case highlighted the need for appropriate mitigation for neutropenia primarily based on characteristics of patients with UC, given that many of those patients exhibit high-risk features, such as age, for neutropenia and subsequent severe infections. To maintain efficacy and overall benefit-risk, a tailored approach for target-specific or payload-specific toxicity management is absolute.

### 3. Early versus late endpoints

Generally, there is no established correlation at a trial-level with response rate and long-term outcomes of PFS and OS. Yet, response rate has been widely used in accelerated approvals in oncology, as it can be directly attributed to the treatment and is clinically relevant. The use of response rate is directed at efficacy and as an endpoint does not account for the impact of toxicity, post-progression events, or the natural history of the disease. Further, response rate can be adequately interpreted in a single-arm trial whereas time-to-event outcomes, such as PFS and OS, cannot. The accelerated approval pathway allows for approvals of drugs in patients with serious and life-threatening diseases that demonstrate an advantage over available therapy on an early endpoint. Sponsors need to account for the limitations of the respective early versus late endpoints and confounding factors impacting the assessment of efficacy and safety. The complexity of ADCs continues to evolve with multi-targeted ADCs and enhanced linkers, which may have unique impacts on tumor kinetics and response rate, leading to uncertainty on the translation to long-term outcomes, requiring a continued, iterative assessment and collaboration.

### 4. Listen to FDA's guidance

FDA oncologists and hematologists see hundreds of clinical pipelines across the field, thus their guidance is paramount with the aim of supporting drug development. A poignant example is the recent July 2025 ODAC for belantamab, in which the voting question was "is the benefit-risk favorable at the proposed dosage in the proposed patient population?"
The intent of the ODAC was to examine the robustness of dose and regimen evaluation in light of FDA feedback throughout the product lifecycle. The ODAC voted negatively regarding the benefit-risk for belantamab at the proposed dosage despite established efficacy in two randomized trials. Thus, early and continued engagement with FDA and strong consideration of their regulatory advice can be paramount throughout the development lifecycle.



"As Dr. Richard Pazdur, Director of the FDA Oncology Center of Excellence, has always emphasized, a failed trial does not necessarily mean a failed drug. At FDA we saw assets rescued by smarter trial design, aggressive toxicity management, or finding the right population. For sponsors, the key is to listen closely, adapt, and build those lessons into the next step."

– Nicholas Richardson, VP Clinical Development, Precision for Medicine

## A Bright Future for ADC Development

The promise of ADCs has been realized with meaningful impact on the oncology treatment landscape. The case studies of GO, belantamab mafodotin, and sacituzumab govitecan highlight consistent lessons for developers: early investment in dosage opens viable paths to support registration, characterization of the toxicity profile should dictate aggressive management strategies, employ early learnings into thoughtful trial designs, engage with FDA early and often throughout the lifecycle, and seek support of key stakeholders and experts that can enhance your FDA collaboration. The momentum for oncology ADCs continues with the potential to revolutionize the treatment paradigm.

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Dr. Richardson also spearheaded initiatives to develop novel endpoints, such as minimal residual disease (MRD) in lymphoma and CLL, helping accelerate drug development. Dr. Richardson is a leading expert in pediatric and adult hematologic malignancies.

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In addition, Dr. Singh was Associate Director for Cancer in Older Adults and Special Populations at the FDA Oncology Center of Excellence (OCE), and was a Fellow at the National Cancer Institute. Dr. Singh is a world-renowned expert in oncology.

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