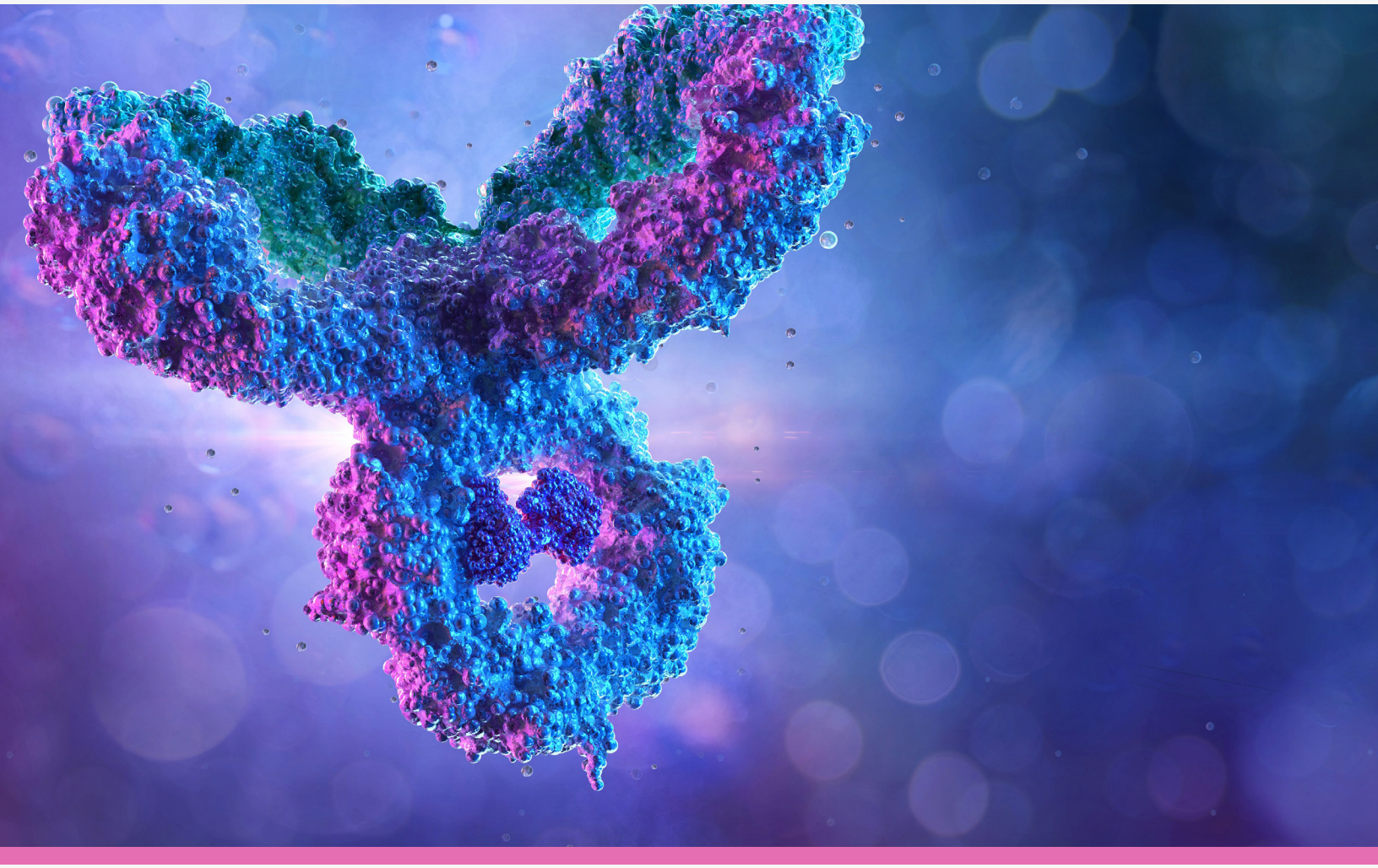
ARTICLE

Pharma Ignite | SCRIP Industry News & Insights

Preparing For The Biosimilar Era Of ADCs And BsAbs In Oncology

Kimberly Salgado, Head of Centre for Biosimilar Drug Development, ICON | SEPTEMBER 2025



Brought To You By SCRIP Industry News & Insights

In Association With ICON BIOTECH

Preparing For The Biosimilar Era Of ADCs And BsAbs In Oncology

Kimberly Salgado, *Head of Centre for Biosimilar Drug Development, ICON*

As oncology biologics face upcoming patent expirations, biosimilar developers must prepare for a new era. This article examines the opportunities and regulatory shifts that will shape the future of ADC, BsAb, and CAR-T biosimilars, and what it will take to lead the next wave.

Upcoming patent cliffs could spell biosimilar opportunities for oncology sponsors. The first wave of treatments coming off patent through 2030 are monoclonal antibodies (mAbs), for which biosimilar development is already well underway. This treatment modality offers more target specificity to cancer cells, facilitating more precise treatment.

The next wave encompasses two modalities for advanced antibody-based therapies, which hold significant promise in oncology: antibody-drug conjugates (ADCs) and bispecific antibodies (BsAbs). Patent expirations for these therapies will begin in 2030.

"Biosimilars development in oncology is entering a phase of strategic and technical evolution – we are now approaching an inflection point from monoclonal antibodies. Next-generation biologic modalities like ADCs and BsAbs replace or augment current mAb therapy," said Kimberly Salgado, head of the Biosimilar Centre for Drug Development at ICON.

Developing biosimilars of these complex compounds will require new bioanalytical tools, regulatory pathways, and navigation of a complicated patent landscape to prove similarity to the reference products.

Still, ADC and BsAb biosimilars offer a high-value opportunity for sponsors and a path to greater access and affordability for patients. The biosimilar market overall is forecasted to reach over $121 billion by 2033.[1]

The Oncology Biosimilars Landscape Today

Monoclonal antibodies have already established a strong foothold in the oncology market for antibody therapies. "The state of oncology biosimilars today is strong and the market has matured. Monoclonal antibodies such as trastuzumab, bevacizumab and rituximab – all of which I have worked on over 10 years ago – have established proof-of-concept for treating oncology indications with biosimilar versions of the originators,' said Salgado. Biosimilars for these treatments are successful when strategically developed and enter the market early. Rituximab biosimilars, for example, account for 41-61% of claims paid by Medicare and Medicaid within four years of entering the US market. By the end of 2024, they made up 76% of the rituximab market.[2,3]

ADCs are an emerging modality that uses a chemical linker to conjugate a monoclonal antibody to a cytotoxic drug. This design allows for treatment delivery directly to the tumor, reducing common issues with traditional chemotherapy, such as toxicity and damage to healthy tissues. As of early 2025, 17 ADCs have been approved globally for cancer treatment, including breast cancer, lymphoma, multiple myeloma, cervical, ovarian, and urothelial cancers.[4,5]

> "Monoclonal antibodies have already established a strong foothold in the oncology market for antibody therapies."

> Multi-target treatments are often better at avoiding drug resistance, a common issue with cancer therapies, while minimizing toxicity and off-target effects.

Patent expirations for ADCs are expected to escalate in the mid-2030s, particularly in 2033-2034. Certain biosimilar-friendly markets have seen local companies develop the world's first biosimilar ADCs, like Ujvira, a biosimilar of the breast cancer ADC trastuzumab emtansine, in India.[6] Yet, no ADC biosimilars have received full approval from the FDA or EMA.

Following up in the later 2030s-2040s are patent expirations for BsAbs that target two specific antigens or epitopes for binding, rather than just one, as with monoclonal antibodies. Multi-target treatments are often better at avoiding drug resistance, a common issue with cancer therapies, while minimizing toxicity and off-target effects.

As of mid-2025, 19 bispecific antibodies have been approved globally, with 12 specifically approved by the FDA for cancer and other indications.[7] Roche's blockbuster therapies Hemlibra and Vabysmo top the market with sales of $5.36 billion and $4.6 billion, respectively, in 2024.[7,8] No BsAb biosimilars have been approved to date, though preclinical studies are underway in lower-barrier markets. Biosimilar developers are closely tracking patent expiries for drugs like Hemlibra.[7]

"The molecules on the horizon are complex—structurally, analytically—and are quite sensitive to the manufacturing process," said Salgado. "They're going to stretch the current biosimilar pathway established for monoclonal antibodies."

The Regulatory Pathway For Biosimilars

The European Medicines Agency (EMA), the Food and Drug Administration (FDA), and the World Health Organization (WHO) have established a regulatory pathway for biosimilar development and approval. This pathway is more complicated for biologics, as, unlike small-molecule drugs, the reference product cannot be precisely replicated. It requires thorough analytical, nonclinical and clinical analysis to compare safety, efficacy, pharmacokinetic similarity and quality with the reference biologic.

Biosimilar development typically begins with analytical studies to establish similarity in structure, function, and quality. If similarity is demonstrated, the product can advance to nonclinical and clinical testing, often with abbreviated study designs focused on pharmacokinetics, safety, and immunogenicity rather than the full-scale trials required for novel biologics. While specific requirements vary by region, global regulators have generally converged on this stepwise, evidence-based approach.

There are additional requirements to achieve interchangeability status, a designation that allows for the substitution of a biosimilar for a reference product without consulting the prescriber. This status typically requires additional data, called switching studies. To date, no oncology biosimilar has received interchangeability status from the FDA,

"Looking ahead over the next 10 years, I think there will be a shift. But it's going to take time," said Salgado. "Within, say, the second half of the decade, I think we might see more regulatory approvals, especially for oncology supportive care drugs where the risk-benefit ratio isn't as great or where an oncology biosimilars drug has been on the market for a while."

In 2024, the FDA released a draft guidance that permits sponsors to provide data supporting their compliance with the switching standards and exemption from conducting additional studies.[9] The change could make it easier for sponsors to achieve interchangeability status going forward. The EMA may follow suit, as a 2025 reflection paper supports a more tailored approach that may not require comparative clinical studies for well-characterized biosimilars.[10]

Yet, Salgado shared that the level of flexibility suggested in these documents has yet to be fully realized. "While we are seeing shifts from the regulatory authorities, when sponsors are submitting their development plans, there are still so many questions and hurdles," she said. "We are in the midst of a transition, and while the pathways have matured for simpler biologics like monoclonal antibodies, the regulatory frameworks are only beginning to adapt to the complexities of ADCS or BsAbs."

> Biosimilar development typically begins with analytical studies to establish similarity in structure, function, and quality.

She imagines that regulatory pathways will likely need to be tailored to each molecule type due to their inherent characteristics and complexities. As of now, regulatory agents appear open to more flexibility, but obstacles remain as regulators navigate the development of advanced biosimilars.

Sponsors Must Move Early—Or Risk Missing The Window

With the patent cliff quickly approaching, sponsors need to start preparing now if they hope to capitalize on the ADC and BsAb biosimilar market. "Being first to market gives sponsors a pricing advantage, formulary access, and clinician familiarity," said Salgado.

Biosimilar development typically takes at least five years and presents unique challenges. ADCs share the same aggregation risk and manufacturing variability seen in monoclonal antibodies. BsAbs also require monitoring for abnormal protein folding, impaired function, and safety during manufacturing, raising development and testing costs. For both modalities, their complex structure triggers a more extensive process to prove similarity with the reference biologic.

> "Biosimilar development typically takes at least five years and presents unique challenges."

"For ADCS and BsAbs, starting now or in the very near future is important because the development timeline includes not just the regulatory requirements, but the time needed for the complex technical, legal, and commercial hurdles that are encountered on the biosimilars racetrack for a complex biologic," said Salgado.

To make the most of patent expirations, sponsors can use the timeline below as a guide:

- **2025:** Start examining the landscape, conduct some feasibility analysis, and initiate the molecule.
- **2026-27:** Develop the cell line and initiate analytical similarity programs.
- **2028:** Progress into non-clinical and toxicology studies and secure regulatory feedback.
- **2029:** Begin clinical PK/PD bridging studies.
- **2030-31:** Prepare and submit regulatory filings.
- **2032-33:** Be first to launch right upon the patent expiry and exclusivity loss.

While CAR T-cell therapies are included in the patent cliff, they remain out of reach for biosimilar development, at least for now. "They fall outside the practical scope of current biosimilar pathways," said Salgado, citing the autologous, patient-specific nature of these treatments and their high manufacturing variability.

Building Trust With Payers, Providers, And The Public

More than 19 million people globally are diagnosed with cancer every year.[11] There is an urgent, unmet need for greater accessibility to cancer treatments. Biosimilars have been shown to increase access, offering potential cost savings anywhere from 20-50% in some cases, according to Salgado. Still, more education is needed within the medical and patient communities.

"Many don't fully understand what biosimilars are and are therefore reticent to be treated with them or to use them, particularly in oncology indications, because they are life-threatening conditions," she added.

Even insurers are more likely to approve name-brand products over biosimilars, though efforts are underway to change that and reduce the cost of healthcare. Biosimilars could save the United States healthcare system $54 billion over the course of a decade, according to one analysis.[12]

"Real-world evidence and post-market data are going to play a really important role in building trust among healthcare providers and payers for these next-generation biosimilars," said Salgado. These studies help validate equivalence in diverse populations, confirm long-term safety, and support interchangeability without compromising efficacy.

Summary

The biosimilar era in oncology is shifting rapidly—from well-characterized monoclonal antibodies to more complex modalities, such as ADCs, BsAbs, and maybe eventually cell therapies. Sponsors who begin preparing now will be best positioned to navigate regulatory evolution, capitalize on first-to-market advantages, and deliver high-quality therapies to patients in need. With early action and strategic rigor, the next decade could usher in a transformative wave of oncology biosimilars—expanding access, reducing costs, and reshaping cancer care.

> "Even insurers are more likely to approve name-brand products over biosimilars, though efforts are underway to change that and reduce the cost of healthcare."

The future of oncology biosimilars: Considerations for development through 2040

Biosimilars have emerged as a significant boon for improving access to cancer treatments for the more than 19 million people diagnosed each year. And as numerous patents for cancer biologics are set to expire through the year 2040, opportunities for developers to use them as reference products for new biosimilars development are abundant.

With the speed of evolution of biologic cancer treatments, as well as regulatory guidance for biosimilars, the biosimilar development process must evolve as well. This whitepaper covers the oncology biologics patent cliff, current regulatory requirements, likely regulatory shift, hurdles and strategies for encouraging biosimilar adoption plus much more.

Download the whitepaper at:
ICONplc.com/future-of-biosimilars

References

1. Insights, Straits Research Private Limited-Garner. Biosimilars Market Size Is Projected to Reach USD 121.88 Billion by 2033, Growing at a CAGR of 15.56%: Straits Research (2025). Biosimilars Market Size Is Projected to Reach USD 121.88 Billion by 2033, Growing at a CAGR of 15.56%: Straits Research (globalnewswire.com)
2. Center for Biosimilars. Biosimilars Drive Cost Savings and Achieve 53% Market Share Across Treatment Areas (2025). Biosimilars Drive Cost Savings and Achieve 53% Market Share Across Treatment Areas (centerforbiosimilars.com)
3. AJMC. Uptake of Rituximab Biosimilars in Medicare and Medicaid in 2019-2022 (2024). Uptake of Rituximab Biosimilars in Medicare and Medicaid in 2019-2022 (ajmc.com)
4. Biopharma PEG Scientific. Global Sales of Antibody-drug Conjugates (ADCs) in 2024 (2025). Global Sales of Antibody-drug Conjugates (ADCs) in 2024 (biochempeg.com)
5. Foley & Lardner LLP. Cancer Drugs (Antibody Drug Conjugates): An FDA Perspective (2024). Cancer Drugs (Antibody Drug Conjugates): An FDA Perspective (foley.com)
6. Generics and Biosimilars Initiative. Trastuzumab Emtansine 'Similar Biologic' Ujvira Launched in India (2021). Trastuzumab Emtansine 'Similar Biologic' Ujvira Launched in India (gabionline.net)
7. Biopharma PEG Scientific. Bispecific Antibodies: Approved Therapies & Emerging Pipeline Drugs (2025). Bispecific Antibodies: Approved Therapies & Emerging Pipeline Drugs (biochempeg.com)
8. Roche Group. Finance Report 2024 (2025). Finance Report 2024 (roche.com)
9. Center for Drug Evaluation and Research. FDA Updates Guidance on Interchangeability (2024). FDA Updates Guidance on Interchangeability (fda.gov)
10. European Medicines Agency. Reflection Paper on a Tailored Clinical Approach in Biosimilar Development (2025). Reflection Paper on a Tailored Clinical Approach in Biosimilar Development (ema.europa.eu)
11. Diehl, T.M. et al. Disparities in Cancer Mortality Worldwide: A Novel Metric for Measuring Global Disparities and Prioritizing Cancer Control Efforts. JCO Glob Oncol 11, e2400336(2025). DOI:10.1200/GO-24-00336
12. AJMC. Utilizing Oncology Biosimilars to Minimize the Economic Burden Associated With Cancer Treatment: Managed Care Considerations (2021). Utilizing Oncology Biosimilars to Minimize the Economic Burden Associated With Cancer Treatment: Managed Care Considerations (ajmc.com)

ICON plc is a world-leading healthcare intelligence and clinical research organisation. From molecule to medicine, we advance clinical research providing outsourced services to pharmaceutical, biotechnology, medical device, and government and public health organisations. We develop new innovations, drive emerging therapies forward and improve patient lives. With headquarters in Dublin, Ireland, ICON employed approximately 39,900 employees in 95 locations in 55 countries as at June 30, 2025.

For further information about ICON, visit **www.iconplc.com/biotech** and **www.iconplc.com/biosimilars**

Pharma Ignite

Pharma Ignite brings you the most up-to-date and informed intelligence in the industry. Our network of industry-leading analysts and partners is pursuing new intelligence in the core areas of life sciences using Citeline's suite of insights products and services – all of which has the power to fuel your organization and projects.

We also provide cutting-edge lead generation and brand programs to help you reach and collaborate with audiences across industry events and digital platforms.