ABI ANALYTICS

RESEARCH & ADVISORY

ONCOLOGY EDITION | 2026

BIOSIMILAR CLIFF LANDSCAPE

The U.S. Cancer Treatment Market

Mapping the loss-of-exclusivity wave reshaping oncology biologics – which blockbuster cancer drugs lose protection, when biosimilars enter, and what it means for developers, payers and investors.

ABI Analytics Research Desk
Prepared June 2026

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EXECUTIVE SUMMARY

Oncology Is Entering Its Second, Larger Biosimilar Cliff

The first wave of cancer biosimilars (2017–2024) has already commoditised a generation of monoclonal-antibody blockbusters. A second, far larger wave – led by the checkpoint inhibitors – now sits directly ahead, with the single biggest loss-of-exclusivity event in oncology history (Keytruda, in excess of $25bn) due in 2028. For biosimilar developers, payers and investors, the next 36 months decide where billions of dollars of margin migrate.

$9.6bn
Global oncology biosimilar market, 2025, on an estimated path to roughly $17.5bn by 2030 (about 12.6% CAGR)

76–90%
Biosimilar volume share already captured on Wave 1 mAbs (rituximab, trastuzumab, bevacizumab)

$25bn+
Keytruda annual revenue exposed at the 2028 U.S. loss of exclusivity, the largest single cliff

50–70%
Typical average-sales-price discount once oncology biosimilars reach steady state

The Core Finding

Oncology biosimilar competition is not a single event but a structured, two-wave phenomenon, and the two waves behave very differently. Wave 1 – the first generation of therapeutic monoclonal antibodies and supportive-care biologics – is now mature, multi-source and price-competitive. It provides an empirical base case: once several biosimilars launch against a molecule, volume migrates rapidly, share crosses 70–90% within two to three years, and the reference price compresses durably. There is no longer any serious question of whether biosimilar substitution happens in oncology; the historical record settles it.

Wave 2 is structurally different and commercially far larger. Where Wave 1 spread moderate revenue across many antibodies, Wave 2 concentrates extraordinary value into a short list of immuno-oncology and next-generation franchises – pembrolizumab, nivolumab, pertuzumab, daratumumab and the bone-health agent denosumab. Three of the largest cliffs cluster in a single year, 2028. Because the revenue is concentrated, each individual cliff becomes a market-moving event in its own right, and the strategic question shifts from breadth of coverage to precision of timing on a handful of molecules.

Why It Matters Now

The defining feature of the period ahead is concentration. A developer, payer or investor does not need to participate across the whole oncology biologic universe to capture most of the value at stake; correctly anticipating two or three molecules – above all pembrolizumab in 2028 – is the larger part of the opportunity. Equally, originators are no longer passive. The defensive playbook refined around the first wave (subcutaneous and fixed-dose reformulation, layered method-of-use patent estates, lifecycle pivots to antibody-drug conjugates and successor molecules, and aggressive payer contracting) is now being deployed pre-emptively against the second. The cliffs are scheduled and datable, but the speed and depth of erosion around each is a live contest.

> **The strategic takeaway.** The oncology biosimilar opportunity is no longer about whether erosion happens – Wave 1 proved it does, quickly and durably. It is about timing and positioning around a short list of very large Wave 2 molecules. The remainder of this report sets out the framework, the molecule-level detail, the competitive dynamics and the stakeholder implications that follow from that single observation.

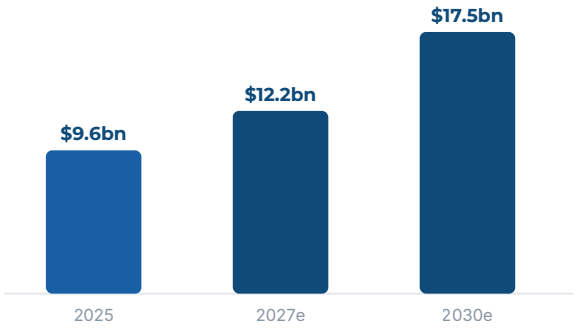
MARKET CONTEXT

How The Oncology Biosimilar Market Is Sized

A biosimilar is a biologic developed to match the safety, efficacy and quality of an already-approved reference biologic. In the United States, biosimilars are licensed under the abbreviated 351(k) pathway created by the Biologics Price Competition and Innovation Act (BPCIA), which also grants a reference biologic twelve years of market exclusivity from first licensure. That twelve-year clock, together with the reference product's patent estate, is what defines the "cliff": the window in which biosimilars can finally enter and compete. Understanding the difference between the two matters. Patents can be numerous, layered and litigated; the twelve-year regulatory exclusivity is a single, predictable date. In practice the effective cliff is set by whichever protection falls last, but the regulatory date provides the floor around which every participant plans.

Oncology is the single largest and fastest-moving biosimilar arena. The FDA has now licensed more than eighty biosimilars across roughly two dozen reference molecules, and cancer therapeutics together with oncology supportive care (the growth-factor and bone-health agents used to manage treatment side-effects) form the largest cluster within that total. The reason is structural: oncology biologics are high-priced, high-volume, clinician-administered products, which makes them both attractive targets for biosimilar developers and high-value savings opportunities for payers. Of the major reference biologics approaching or past exclusivity loss this decade, oncology accounts for the highest concentration of multi-billion-dollar franchises.

Market Size And Trajectory



Global oncology biosimilars market (USD), ~12.6% CAGR

ABI Analytics synthesis of public FDA approval records and prevailing industry estimates. North America is the largest single region, around 38% of value.

Wave 1 Biosimilar Penetration

Biosimilar share of molecule volume, U.S., recent

Once three or more biosimilars launch against a molecule, share typically crosses 70% within two to three years. ABI Analytics analysis.

Cost Dynamics And Why Oncology Erodes Quickly

Oncology biosimilars list at meaningful discounts and erode the reference average sales price (ASP) durably. Reported steady-state ASP discounts run in a 50–70% band; in the two years after multi-source competition arrived, reference-brand ASPs for rituximab and trastuzumab fell by roughly a third and a quarter respectively, and continued to grind lower thereafter. Two features of oncology economics explain the speed. First, most oncology biologics are administered by clinicians under the medical benefit ("buy-and-bill") and reimbursed at ASP plus a percentage, so once a biosimilar is stocked and protocolised, switching is an institutional decision rather than millions of individual prescriptions. Second, large integrated providers, group purchasing organisations and pathways vendors actively steer to the lowest-cost equivalent, compressing the time between launch and majority share. The combination means that, unlike some retail-pharmacy categories where brand loyalty slows erosion, oncology biosimilar uptake is fast and largely irreversible once underway.

THE FRAMEWORK

A Two-Wave Structure, Not A Single Event

The most useful way to read oncology biosimilars is as two distinct waves with different molecules, different economics and different strategic stakes. Conflating them is the most common analytical error; separating them is the key to timing.

Wave 1 – the first-generation antibodies and supportive-care agents. This wave covers the molecules whose U.S. exclusivity lapsed between roughly 2015 and the early 2020s: the anti-HER2 antibody trastuzumab, the anti-VEGF antibody bevacizumab, the anti-CD20 antibody rituximab, and the supportive-care biologics filgrastim, pegfilgrastim and epoetin alfa. It is now mature. Each large molecule attracted multiple biosimilar entrants, share migrated quickly, and pricing settled into durable competition. Wave 1 is valuable less for the revenue still in play and more for what it proves: in oncology, biosimilar substitution is fast, deep and permanent once competition is multi-source.

Wave 2 – the immuno-oncology and next-generation franchises. This wave covers the molecules losing exclusivity from the mid-2020s through the early 2030s, and it is where the value now sits. It is led by the immune-checkpoint inhibitors pembrolizumab and nivolumab, alongside the anti-HER2 antibody pertuzumab, the anti-CD38 antibody daratumumab, and the bone-health agent denosumab. Two characteristics make Wave 2 different in kind, not just degree. First, the revenue is extraordinarily concentrated: a handful of molecules carry tens of billions of dollars of global sales, with pembrolizumab alone exceeding $25bn. Second, the cliffs cluster, with several of the largest falling within 2028. The practical consequence is that each Wave 2 cliff is an individually material, market-moving event, and that anticipating the timing of two or three molecules captures the majority of the opportunity.

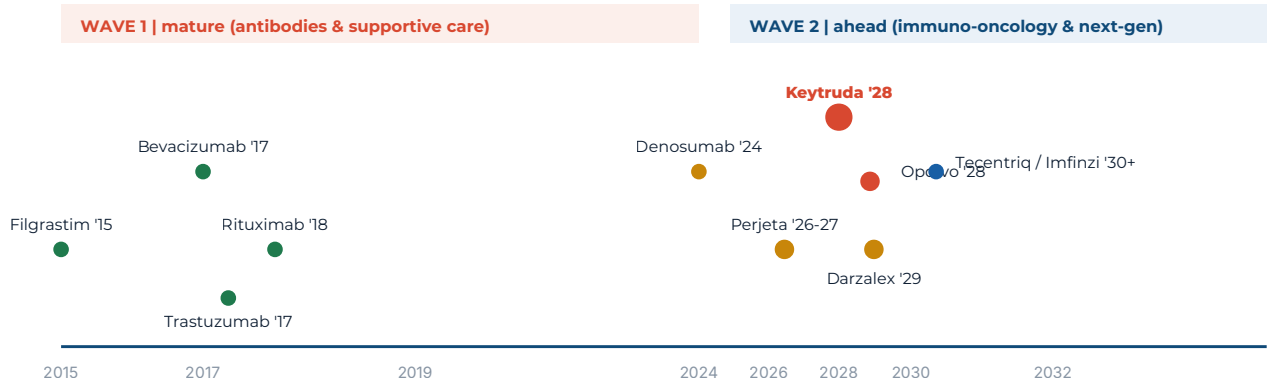
How To Use The Two-Wave Lens

- **Treat Wave 1 as the base case.** Its share-shift and price-erosion curves are the most reliable available template for how each Wave 2 cliff will unfold once multi-source competition arrives.
- **Treat Wave 2 as a concentration play.** Coverage breadth matters far less than precision on the largest molecules; pembrolizumab in 2028 is the single most consequential event.
- **Watch the gap between the regulatory date and real entry.** The twelve-year exclusivity sets the floor; patent litigation, settlements and at-risk launches determine how much later, or occasionally earlier, true competition begins.

THE CLIFF TIMELINE

When The Major Oncology Biologics Lose Exclusivity

Two waves, one decade. Wave 1 (the antibodies and supportive-care agents) is essentially complete. Wave 2 (the immuno-oncology and next-generation franchises) concentrates far more revenue into the 2026–2032 window.



First U.S. biosimilar approval (Wave 1) | expected U.S. loss-of-exclusivity window (Wave 2). Marker size approximates relative reference-revenue exposure.

Keytruda is the fulcrum. At more than $25bn in annual sales, pembrolizumab's 2028 U.S. cliff is the largest single biosimilar opportunity ever created. Multiple developers have signalled FDA filings in 2026–2027. The originator is defending with a subcutaneous formulation, fixed-dose combinations and a method-of-use patent estate spanning more than forty indications – a template every Wave 2 originator is now studying.

Reading The Timeline

The chart compresses two different things onto one axis, and the distinction is deliberate. For Wave 1, the markers show the date of first U.S. biosimilar approval, because for those molecules the relevant question is already settled and the interesting fact is how long competition has been compounding. For Wave 2, the markers show the expected loss-of-exclusivity window, because for those molecules the cliff has not yet arrived and timing is the live variable. The visual story is the rightward stacking around 2028: where Wave 1 entries were spread across several years and several mid-sized molecules, Wave 2 bunches three of the largest franchises in the industry into a narrow window. That clustering is what turns a steady commercial trend into a set of discrete, datable, high-stakes events.

It is also why the gap between the regulatory date and the moment of real competition matters so much for Wave 2. A single year's slippage on pembrolizumab is worth billions of dollars to the originator and to every biosimilar developer queuing behind it. The patent dance, settlement agreements and the willingness of any developer to launch at risk will determine whether 2028 is a hard wall or a gradual ramp – and that uncertainty, rather than the existence of the cliff, is where the analytical and commercial contest now lies.

U.S. Oncology Biosimilar Landscape

Reference biologics and their FDA-approved biosimilars | As of June 2026

ABI ANALYTICS

Class	Anti-Cancer Monoclonal Antibodies					Immune Checkpoint Inhibitors		Supportive Care			Bone Health
Molecule	Trastuzumab	Bevacizumab	Rituximab	Pertuzumab	Daratumumab	Pembrolizumab	Nivolumab	Pegfilgrastim	Filgrastim	Epoetin alfa	Denosumab
Reference product	HERCEPTIN Roche/Genentech	AVASTIN Roche/Genentech	RITUXAN Roche/Biogen	PERJETA Roche/Genentech	DARZALEX Johnson & Johnson	KEYTRUDA Merck	OPDIVO Bristol Myers Squibb	NEULASTA Amgen	NEUPOGEN Amgen	EPOGEN/PROCRIT Amgen/J&J	PROLIA/XGEVA Amgen
Biosimilars Mfr & FDA approval	OGIVRI Biocon/Viatris Dec 2017	MVASI Amgen Sep 2017	TRUXIMA Teva/Celltrion Nov 2018	No biosimilar yet Expected 2026-27	No biosimilar yet Expected ~2029	In development Expected 2028	In development Expected 2028	FULPHILA Viatris Jun 2018	ZARXIO Sandoz Mar 2015	RETACRIT Pfizer May 2018	JUBBONTI/WYOST Sandoz Mar 2024
	HERZUMA Celltrion Dec 2018	ZIRABEV Pfizer Jun 2019	RUXIENCE Pfizer Jul 2019					UDENYCA Coherus Nov 2018	NIVESTYM Pfizer Jul 2018		OSPOMYV/XBRYK Samsung Bioepis 2024
	ONTRUZANT Organon Jan 2019	ALYMSYS Amneal Apr 2022	RIABNI Amgen Dec 2020					ZIEXTENZO Sandoz Nov 2019	RELEUKO Amneal Feb 2022		CONEXXENCE Fresenius 2025
	TRAZIMERA Pfizer Mar 2019	VEGZELMA Celltrion Sep 2022						NYVEPRIA Pfizer Jun 2020			STOBOCLO Celltrion 2025
	KANJINTI Amgen Jun 2019	AVZIVI Sandoz Dec 2023						FYLNETRA Amneal May 2022			
	HERCESSI Accord Apr 2024							STIMUFEND Fresenius Sep 2022			

Approved & launched biosimilar

In development / not yet launched

Interchangeable (FDA)

Source: FDA Purple Book & biosimilar approval records | ABI Analytics Research Desk

MOLECULE LANDSCAPE | WAVE 1

Mature Cliffs: Already Commoditised

These reference biologics have faced U.S. biosimilar competition for years. They are the empirical base case for how Wave 2 cliffs will most likely unfold: multiple entrants, rapid share migration and durable price compression.

REFERENCE BRAND	MOLECULE	ORIGINATOR	FIRST U.S. BIOSIMILAR	BIOSIMILARS APPROVED	SHARE	STATUS
Herceptin	Trastuzumab	Roche / Genentech	2017 (Ogivri)	6: Ogivri, Herzuma, Ontruzant, Trazimera, Kanjinti, Hercessi	~86%	Eroded
Avastin	Bevacizumab	Roche / Genentech	2017 (Mvasi)	5: Mvasi, Zirabev, Alymsys, Vegzelma, Avzivi	~90%	Eroded
Rituxan	Rituximab	Roche / Biogen	2018 (Truxima)	3: Truxima, Ruxience, Riabni	~76%	Eroded
Neulasta	Pegfilgrastim	Amgen	2018 (Fulphila)	6+: Fulphila, Udenyca, Ziextenzo, Nyvepria, Fylnetra, Stimufend	~74%	Eroded
Neupogen	Filgrastim	Amgen	2015 (Zarxio)	3: Zarxio, Nivestym, Releuko	~81%	Eroded
Epogen / Procrit	Epoetin alfa	Amgen / J&J	2018 (Retacrit)	1: Retacrit (interchangeable)	Established	Eroded

Zarxio (filgrastim-sndz, 2015) was the first biosimilar of any kind approved in the United States. Share figures are approximate U.S. volume shares from recent reporting, presented as ABI Analytics estimates. Supportive-care agents are used throughout oncology to manage chemotherapy side-effects and are included for completeness.

What The First Wave Establishes

Across all six molecules the pattern is consistent enough to be treated as a rule. Entry is multi-source: each large therapeutic antibody attracted three to six biosimilars within a few years of the first approval, and the supportive-care agents attracted even more. Share migrates quickly: once competition was multi-source and products were stocked into institutional protocols, biosimilar volume crossed the 70–90% mark within two to three years. Price compression is durable: reference ASPs fell sharply on first competition and continued to decline, with net discounts settling in the 50–70% range. And originators retreat rather than defend the original presentation: the typical response was to pivot to a differentiated form, a subcutaneous version or a combination, conceding the original molecule's volume to biosimilars while attempting to hold a defended niche.

The anti-HER2 and anti-VEGF franchises (trastuzumab and bevacizumab) are the cleanest illustrations, having reached roughly 86% and 90% biosimilar share. Rituximab eroded somewhat more slowly, to around 76%, reflecting a more complex mix of haematology and immunology indications and more deliberate switching in certain disease settings – a useful reminder that indication mix and clinical conservatism can modulate the speed, though not the direction, of erosion. The supportive-care agents, where clinical interchangeability concerns are lower, eroded fastest of all. The implication for Wave 2 is direct: the question is never whether a molecule erodes once multi-source competition arrives, but how quickly, and the answer depends largely on indication complexity and the number of competing entrants.

MOLECULE LANDSCAPE | WAVE 2

The Cliffs Ahead: Where The Value Sits

Wave 2 concentrates extraordinary revenue into a short list of immuno-oncology and next-generation molecules. These are the franchises that will define oncology biosimilar economics through 2032.

REFERENCE BRAND	MOLECULE	ORIGINATOR	APPROX. REF. REVENUE	U.S. LOE WINDOW	BIOSIMILAR STATUS	URGENCY
Keytruda	Pembrolizumab	Merck	$25bn+ (global)	**2028**	Multiple in development; FDA filings expected 2026–27	Critical
Opdivo	Nivolumab	Bristol Myers Squibb	~$9bn	**2028** (EU 2030)	In development	Critical
Perjeta	Pertuzumab	Roche / Genentech	~$4bn	**2026–27**	Earliest Wave 2 entry; programs active	Imminent
Darzalex	Daratumumab	Johnson & Johnson	~$11bn	**2029** (EU 2031)	Early development	Near-term
Xgeva / Prolia	Denosumab	Amgen	~$6bn combined	2024–25 (live)	First biosimilars approved 2024; multiple followers, several interchangeable	Open now
Tecentriq	Atezolizumab	Roche / Genentech	~$4bn	2030+	Early	Watch
Imfinzi	Durvalumab	AstraZeneca	~$4bn	2030+	Early	Watch
Cyramza	Ramucirumab	Eli Lilly	~$1bn	2030+	Early	Watch

Revenue figures are approximate global reference-brand sales drawn from public company disclosures, presented as ABI Analytics estimates; LOE windows are U.S. and reflect the BPCIA reference-product exclusivity and published patent-cliff analysis. Actual biosimilar launch timing depends on patent litigation, settlements and at-risk-launch decisions. Brands shown are reference (originator) products.

Pembrolizumab (Keytruda) | The Defining Cliff

No single event in the history of biologic competition compares to pembrolizumab's 2028 U.S. exclusivity loss. As the best-selling pharmaceutical in the world, with more than $25bn in annual sales spread across an exceptionally broad set of oncology indications, it concentrates more revenue into one cliff than the entirety of Wave 1 combined. The originator's defense is the most sophisticated yet assembled: a subcutaneous formulation designed to shift volume to a freshly protected presentation before the intravenous form is exposed, fixed-dose and combination filings, and a method-of-use patent estate tied to dozens of approved indications that can extend protection on specific clinical uses beyond the core date. For biosimilar developers, the prize is large enough that several are already in clinical development with filings expected in 2026–2027; the contest will be decided less by who can make the molecule than by who can navigate the patent estate and reach the market first.

Nivolumab, Pertuzumab And Daratumumab | The Surrounding Cluster

Nivolumab (Opdivo) shares the 2028 U.S. window, adding roughly $9bn of exposed revenue and making 2028 a year in which two of the largest immuno-oncology franchises open at once. Pertuzumab (Perjeta) is the earliest Wave 2 entry point, with biosimilar competition expected as soon as 2026–2027; as an anti-HER2 antibody it sits in the same clinical territory that Wave 1 trastuzumab biosimilars already dominate,

which should ease physician acceptance and accelerate uptake. Daratumumab (Darzalex), the anti-CD38 backbone of modern multiple-myeloma therapy, carries around $11bn of global revenue with a U.S. window near 2029, making it the largest haematology-specific opportunity of the wave. Denosumab (Xgeva in oncology, Prolia in bone health) is already live: its first biosimilars were approved in 2024, several with interchangeability, and it offers a real-time preview of how a Wave 2 bone-health cliff erodes.

Concentration is the opportunity. Where Wave 1 spread modest revenue across many antibodies, Wave 2 stacks more than $50bn of global reference revenue into roughly eight molecules, three of which cliff in a single year. A developer or investor does not need broad coverage to participate; correctly timing two or three molecules is the larger part of the game.

COMPETITIVE DYNAMICS

Who Is Building The Biosimilars

Oncology biosimilar supply has consolidated around a set of scaled developers with the manufacturing, regulatory and litigation capacity to compete in clinician-administered markets. The same names recur across molecules, and they increasingly partner to share development cost and de-risk the patent dance. The landscape infographic earlier in this report maps every approved product to its developer; the analysis below draws out the strategic shape behind it.

Leading Developers

- **Amgen** – Mvasi, Kanjinti, Riabni; deep antibody capability and its own originator franchises to defend
- **Sandoz** – first-mover in U.S. biosimilars (Zarxio); now leading the denosumab wave
- **Celltrion** – Truxima, Herzuma, Vegzelma; vertically integrated manufacturer
- **Pfizer** – Zirabev, Ruxience, Trazimera, Nyvepria; broad oncology portfolio
- **Samsung Bioepis / Organon** – Ontruzant and a deepening pipeline
- **Teva, Biocon, Accord, Fresenius Kabi, Coherus, Amneal** – expanding oncology and supportive-care positions

How Originators Defend

- **Reformulation** – subcutaneous and fixed-dose versions that carry fresh exclusivity and shift volume before the cliff
- **Patent layering** – method-of-use patents tied to many indications, plus formulation and dosing-regimen patents
- **Lifecycle pivots** – antibody-drug conjugates and successor molecules that move revenue ahead of exclusivity loss
- **Contracting** – payer rebates, bundling and pathway placement to slow institutional switching

The competitive structure has two implications worth drawing out. First, scale and integration increasingly win: the developers that recur across molecules are those that can carry the cost of multiple parallel programs and absorb litigation risk, which is steadily raising the barrier to entry and concentrating supply. Second, originators have professionalised their defense. Where the first wave caught some incumbents flat-footed, Wave 2 originators are deploying the full reformulate-layer-pivot-contract playbook pre-emptively, which is likely to make the early months of each Wave 2 cliff more gradual than Wave 1's, even as the eventual destination – majority biosimilar share – remains the same.

STRATEGIC IMPLICATIONS

What The Cliff Landscape Means By Stakeholder

STAKEHOLDER	IMPLICATION AND THE ACTION IT SUGGESTS
Biosimilar Developers & Generics BD	The 2028 cluster (pembrolizumab, nivolumab) is the defining commercial event of the decade and programs must already be in clinic to participate. Pertuzumab (2026–27) is the nearest entry point and sits in familiar anti-HER2 territory. Prioritise molecules by revenue-at-risk weighted against the number of competing filings; a crowded field of five or more entrants will compress price faster than scale economics can absorb.
Originators & Pharma Strategy	Model revenue cliffs molecule-by-molecule and pre-deploy defenses (subcutaneous and fixed-dose reformulation, lifecycle ADCs, method-of-use estates and contracting) twenty-four to thirty-six months ahead. Wave 1 shows that undefended franchises lose the majority of volume within two to three years of multi-source entry; the goal of defense is not to prevent erosion but to slow it and to relocate revenue to a protected presentation.
Payers, Providers & PBMs	Each cliff is a budget event. Formulary design, buy-and-bill protocol updates and pathway steering set in advance of 2028 can capture 50–70% ASP savings on some of the largest oncology spend categories. The institutions that pre-position protocols capture savings fastest; those that wait cede a year or more of avoidable cost.
Investors	Cliffs are scheduled, datable catalysts. The structure supports being long biosimilar developers and cautious on exposed originators around datable loss-of-exclusivity windows, while watching the patent dance, settlement dates and at-risk-launch signals that determine timing. Pembrolizumab 2028 is a multi-year, multi-name thesis rather than a single trade.

OUTLOOK

Scenarios And What To Watch Into 2028

The existence and approximate timing of the Wave 2 cliffs is settled. The open question is the speed and depth of erosion around each, which we frame as three scenarios anchored on the pembrolizumab cliff.

Base Case | Orderly, Multi-Source Entry From 2028

Settlements between the originator and the leading developers establish defined U.S. entry dates around the 2028 exclusivity loss; three to five biosimilars launch within the following eighteen months; and erosion follows the Wave 1 template, reaching majority biosimilar share within two to three years. Subcutaneous reformulation retains a meaningful but minority slice of volume for the originator. This is the most probable path and the one around which most participants should plan.

Upside For Biosimilars | Early Or At-Risk Entry

One or more developers prevail in litigation or launch at risk slightly ahead of the consensus window, or the originator's subcutaneous switch underperforms. Erosion is faster and deeper than the base case, payer savings arrive sooner, and the originator's revenue decline is steeper. This scenario rewards the developers positioned to move first and the payers who have pre-built protocols.

Downside For Biosimilars | Effective Originator Defense

A successful subcutaneous and fixed-dose switch, combined with method-of-use patents that fence off specific high-value indications and aggressive contracting, slows biosimilar uptake materially in the first two years. The cliff still arrives, but its near-term financial impact is muted and spread over a longer period. This scenario most rewards originators and penalises developers who over-invested in a single crowded molecule.

What To Watch

- **Biosimilar FDA filings and acceptances** for pembrolizumab and nivolumab through 2026–2027 – the leading indicator of who reaches the 2028 window.
- **Settlement announcements and patent-dance milestones** that convert the regulatory date into a real entry date.
- **Subcutaneous switch uptake** on the major immuno-oncology brands – the clearest signal of how much volume originators can relocate.
- **Pertuzumab and denosumab erosion curves** as the earliest, real-time previews of Wave 2 behaviour.

METHODOLOGY

How This Report Was Built

This landscape is constructed on a spine of primary FDA registry data and ABI Analytics' own analysis. The loss-of-exclusivity framework follows the FDA's own definitions of reference-product exclusivity under the BPCIA (twelve years from first licensure) together with listed patent and exclusivity expiry. Market-size and share figures are presented as ABI Analytics estimates that synthesise the public record; they are indicative and intended to frame magnitude rather than to serve as point forecasts.

Primary Data Spine

- **FDA Purple Book** – the official registry of licensed biological products and biosimilars, including reference versus 351(k) status, licensure dates, exclusivity and interchangeability designations.
- **FDA Orange Book and Drugs@FDA (openFDA)** – small-molecule patent and exclusivity context and approval history used to frame the regulatory mechanics.
- **FDA biosimilar approval records** – the roster of approved biosimilars by molecule and approval date that underpins the landscape infographic.