WHITE PAPER

The state of oncology in 2026

A strategic outlook for global and U.S. oncology leaders navigating portfolio growth, innovation, access and commercialization complexity

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Key takeaways

- Oncology growth is shifting toward subtype-led strategies, earlier-stage disease and tumor segments where incidence, survival and unmet need create clearer opportunity.
- As development crowds around derisked biology and loss of exclusivity (LOE) risk grows, resilient portfolios will require tighter links between target choice, modality choice, evidence strategy and external innovation.
- Regional and affiliate success increasingly depends on incorporating local cancer burden, pricing exposure, regulatory expectations and launch sequencing into strategy earlier in the product life cycle.
- In the U.S., commercial performance will depend on tailoring launch investment, removing barriers across the patient journey and addressing access, affordability, health system capacity and workflow friction.
- Policy and LOE pressures are compressing revenue windows, making pricing, indication strategy, launch sequence and value-protection tactics more interdependent.

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Strategic outlook for global oncology leaders

Three questions sit at the top of every global oncology leadership team's agenda—and the answers are becoming more complex every day. Those questions are:

- The late-stage value pool is shrinking, but we must continue to grow. Where do we play?
- How do we build a differentiated portfolio amid the crowding around derisked biology, uncertainty with novel modalities and a growing substrate of external innovation?
- How do we enable success for the affiliates, payers, regulators and health systems whose decisions now shape clinical development and pricing strategy from the start?

In this chapter of our report, we will articulate our point of view on each of these essential questions.

How can global oncology leaders find growth in oncology?

Oncology growth is concentrated in cancers where burden—measured as incidence times survival—is accelerating fastest and outcomes have not kept pace. The next wave of oncology value creation will come from identifying and prioritizing the right subsegments within these cancers.

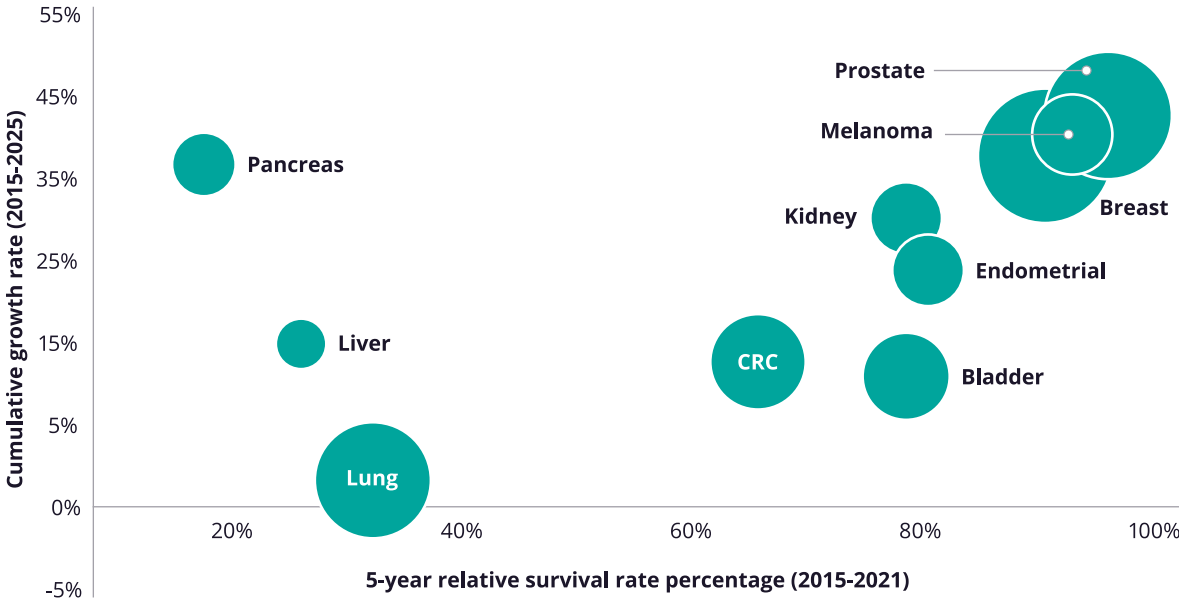
Consider the interplay of cancer incidence, growth and survival

When you stratify tumor types by incidence, growth and survival, you can better understand how to categorize tumor types for disease area strategy. Using these lenses, three strategic archetypes emerge, as we can see in Figures 1 and 2:

- **Higher incidence + higher survival:** These are large markets with meaningful unmet need in select subsegments, such as breast cancer, prostate cancer and chronic lymphocytic leukemia (CLL).
- **Higher incidence + lower survival:** These are large, poorly served populations that need better therapies, such as small-cell lung cancer (SCLC), CAR-T or T-cell engager-refractory non-Hodgkin lymphoma (NHL) and driver-mutation wild-type acute myeloid leukemia (AML).
- **Lower incidence + rapid growth + lower survival:** These represent a risk of cancer burden accumulating if underinvestment continues, which is what we've seen in pancreatic cancer. Research presented at ASCO 2026 showed just how valuable this approach is. In the RASolute 302 trial, daraxonrasib demonstrated a massive benefit over standard of care in previously treated metastatic pancreatic ductal adenocarcinoma (PDAC).

FIGURE 1:

Solid tumor incidence, growth rate and survival

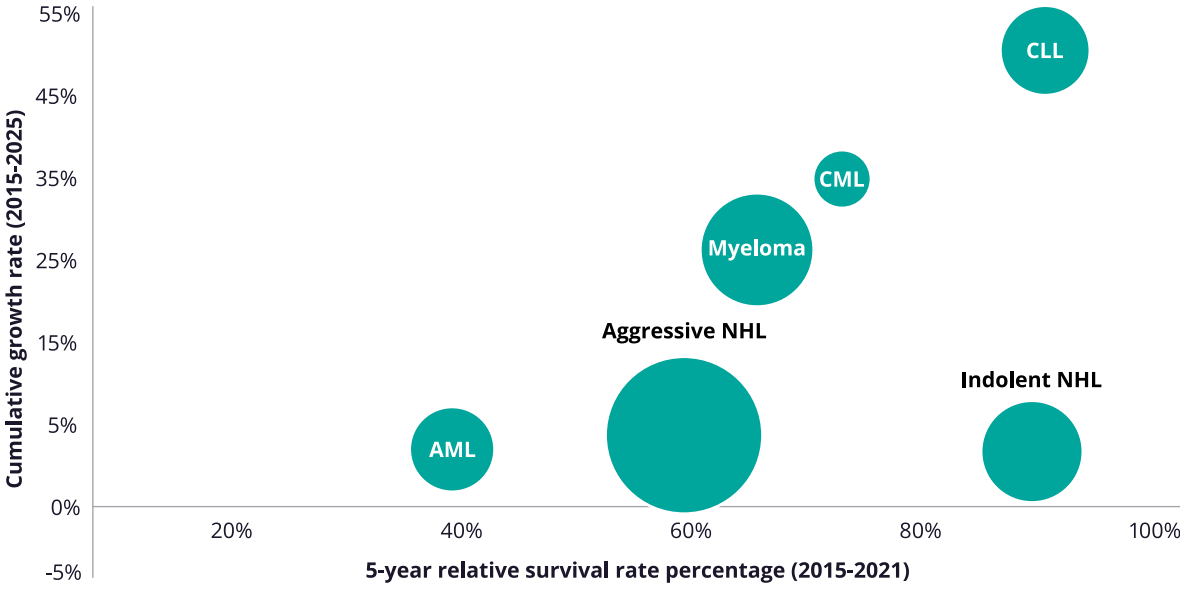


Notes: Size of bubble corresponds to disease incidence (n size) in 2025. CRC = Colorectal cancer.

Source: SEER, American Cancer Society Reports

FIGURE 2:

Hematologic malignancy incidence, growth rate and survival



Notes: Size of bubble corresponds to disease incidence (n size) in 2025. For certain tumor types with both indolent and aggressive NHL, the survival rates used in the calculations are not strictly from 2015-2021. CML = Chronic myeloid leukemia.

Sources: SEER, American Cancer Society Reports

Implications:

These archetypes suggest oncology organizations should take a subtype-led approach to disease area and portfolio strategy. The goal is to identify where unmet need is concentrated, where biology is actionable and where novel therapies are most likely to improve outcomes. Each example highlights a different way to apply this framework in oncology:

- In high-incidence or high-prevalence cancers with relatively good overall outcomes, better subtyping can identify high-unmet-need segments worth prioritizing. A good example is HR+/HER2- breast cancer, where actionable genomic alterations, such as ESR1, PIK3CA, AKT1 and PTEN, as well as biomarkers such as HER2-low, have disrupted a paradigm of endocrine therapy retreatment and chemotherapy, improving outcomes in the process.
- A fuller understanding of disease biology in wild-type subtypes of high-unmet-need cancers (like lung cancer or AML) can inform therapeutic innovation and target selection.
- Focusing novel medicines on particularly high-unmet-need tumor types can improve outcomes where existing therapies have failed to keep pace. In pancreatic cancer, daraxonrasib and other pan-RAS therapies currently under development are positioned to become effective targeted therapies. In SCLC, DLL3-targeted medicines have enabled tumor-selective targeting.

Aim to improve rates of early diagnosis

Early detection is a major lever for improving outcomes, but the opportunity is increasingly about precision, not scale and progress is uneven (see Figure 3).

Early-stage diagnosis rates have plateaued in high-incidence and relatively easy-to-detect cancers such as breast, prostate and melanoma. Many high-incidence cancers including lung, colorectal, pancreatic and liver are still predominantly diagnosed in later stages, despite improvements in early detection for lung and pancreatic cancer in the last 15-plus years.

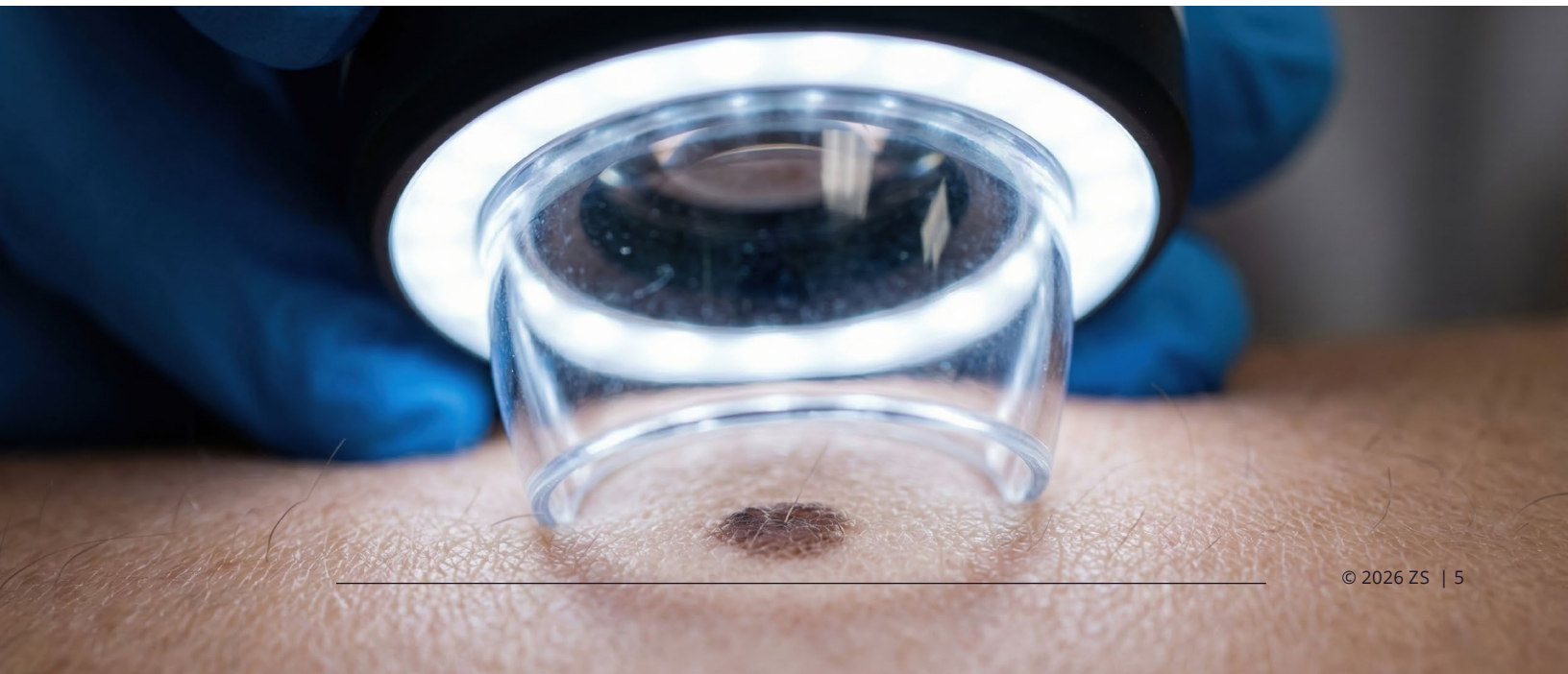
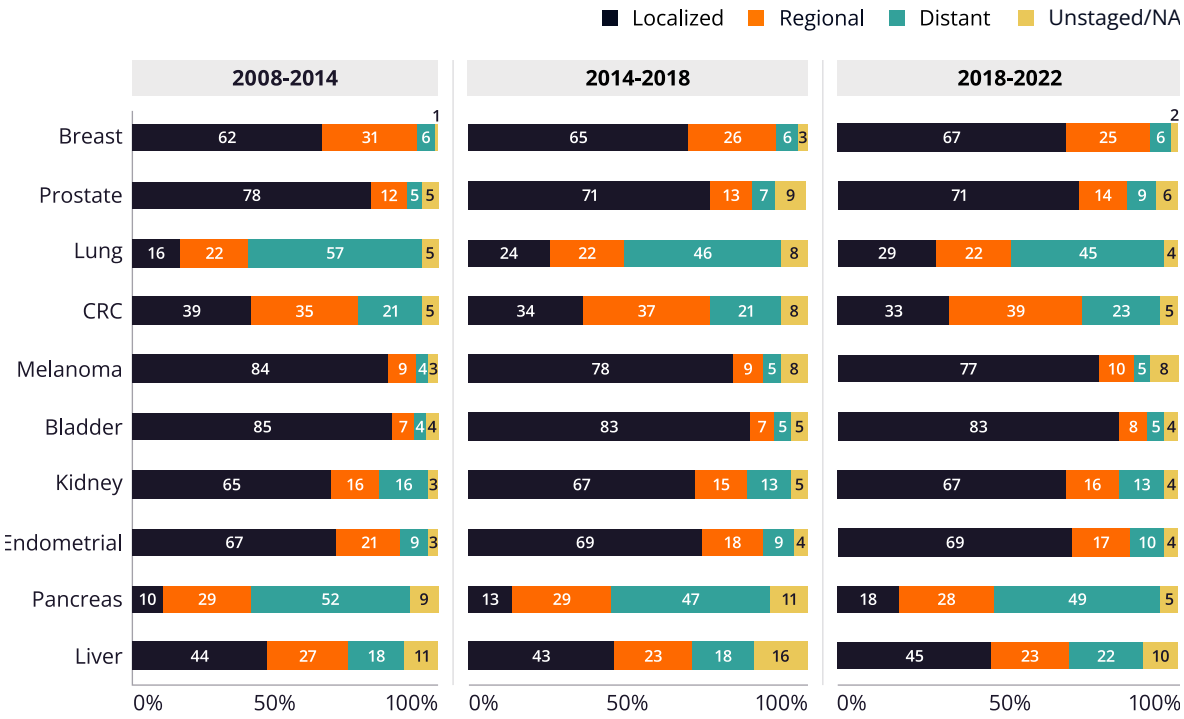


FIGURE 3:

Staging at diagnosis, over time, in the U.S.



Source: American Cancer Society; Siegel et al. (2026)

But broader screening innovation has faced challenges. In the recently published NHS-Galleri trial, a multicancer screening program failed to meet its primary endpoint of a statistically significant reduction of late-stage cancer diagnoses. GRAIL designed this clinical trial to demonstrate population-level impact. However, by pursuing a broad patient population, their screening program failed to significantly reduce stage 3-4 diagnosis rates.

There are bright spots, however, where AI systems like FDA-approved Clairity Breast, MIT Jameel Clinic's Sybil AI model and Optellum's imaging and clinical decision support platform all improved early-stage detection.

Implications:

The failure of broad multicancer screening to shift late-stage diagnosis suggests that focusing purely on screening more people is the wrong goal. The future of early detection is narrower, risk-stratified and deeply integrated into care—not mass-market diagnostics. It will require:

- Focusing on cancers where early detection lags, such as in lung, pancreatic and liver cancers.
- Developing targeted screening strategies for populations at higher risk of developing cancer, as shown by ASCO 2026 data on the ClearNote Health Avantect® Pancreatic Cancer Test for individuals at high risk for developing pancreatic cancer.

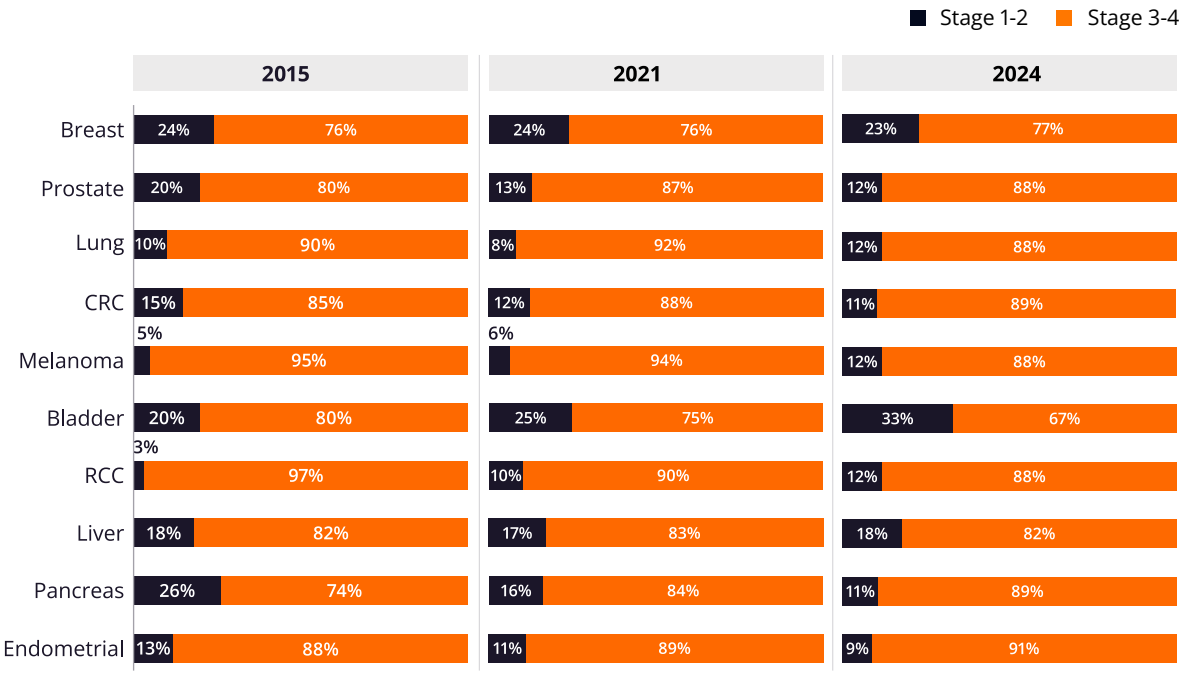
- Integrating screening into longitudinal patient management, not one-time testing.
- Leveraging AI models to increase the sensitivity of cancer detection.

Increase focus on early-stage disease

Despite blockbuster oncology medicines like Keytruda, Opdivo, Imfinzi, Tecentriq, Padcev and others moving into curative settings, cancer medicine development in the aggregate has not meaningfully shifted toward early stages, as seen in Figure 4. One exception is bladder cancer, where shortages of Bacillus Calmette-Guérin have led to increased development in nonmuscle invasive bladder cancer.

FIGURE 4:

Global clinical development by stage in key tumor types



Notes: Trial counted by year started. If a trial is ongoing in multiple tumor types, it has been counted for each tumor type. Likewise, if a trial is evaluating both early (stage 1-2) and late (stage 3-4) stage of the disease, it has been counted in both stages. Percentages may not equal 100% due to rounding. RCC = Renal cell carcinoma.

Sources: ZS analysis, Trialtrove (data extracted in March 2026)

Implications:

Late-stage disease has become the industry's comfort zone, rather than its growth engine. This missed opportunity is leaving early-stage disease to a handful of established blockbusters while novel modalities pile up in metastatic settings. Companies that want to adopt a defensible position by 2030 should:

- Seek more opportunities to move established medicines into early stage. Plenary sessions at ASCO 2026 demonstrated this focus through PROTEUS in high-risk localized prostate cancer and LIBRETTO-432 in stage 1B-3A RET fusion-positive nonsmall cell lung cancer.
- Gain a better understanding of which modalities may be best suited for early stage from the start of their development.
- Use molecular or minimal residual disease monitoring for assessment of response and recurrence to accelerate clinical development, accompanied by collaboration with health technology assessments to align expectations for evidence.

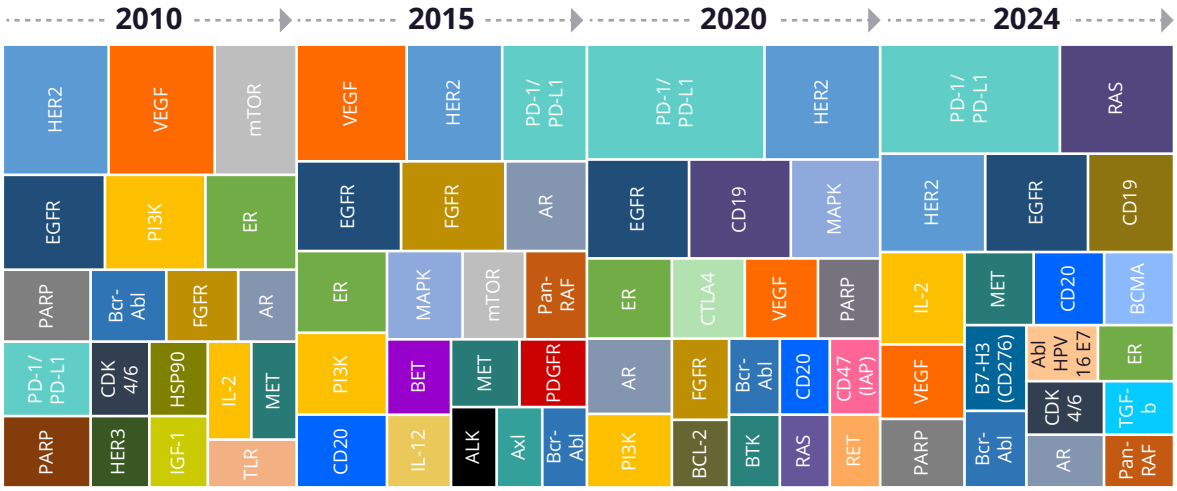
How can global oncology leaders build resilient portfolios?

Over the past 15 years, oncology R&D has clustered around a set of derisked targets (Figure 5), with the average number of assets per target doubling since 2010. Despite AI reducing target identification timelines, novel targets have yet to appreciably shift the balance of development.

This reflects rational capital allocation but also signals crowding and diminishing differentiation. In essence, target derisking has succeeded but commercial derisking has not.

FIGURE 5:

Medicines per target for top 30 intracellular and extracellular targets



Source: ZS analysis, Trialtrove (data extracted in July 2025)

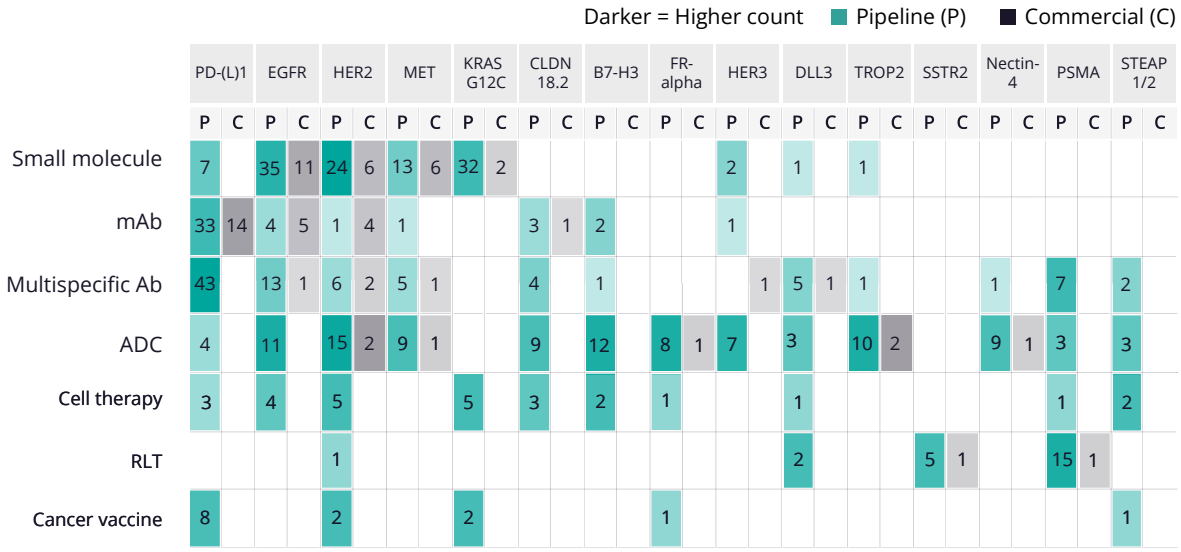
Expand derisked targets into underpenetrated modalities

When we examine targets by modality (see Figure 6), we can identify potential white spaces for derisked targets across solid tumors and hematological malignancies:

- CD20 is an attractive target in B-cell malignancies, though we don't see as much cell therapy activity as with CD19.
- FRα, Nectin-4 and TROP2 appear underexplored by modality.
- Radioligand therapies can deliver comparable breadth as antibody drug conjugates (ADCs) across common solid tumor targets.
- Cancer vaccines need more regulatory validation before becoming an attractive modality for target expansion. Research presented at ASCO 2026 demonstrated some promise here, with KEYNOTE-942 five-year follow-up showing sustained efficacy for intismeran autogene + pembrolizumab in resected high-risk, stage 3-4 melanoma.

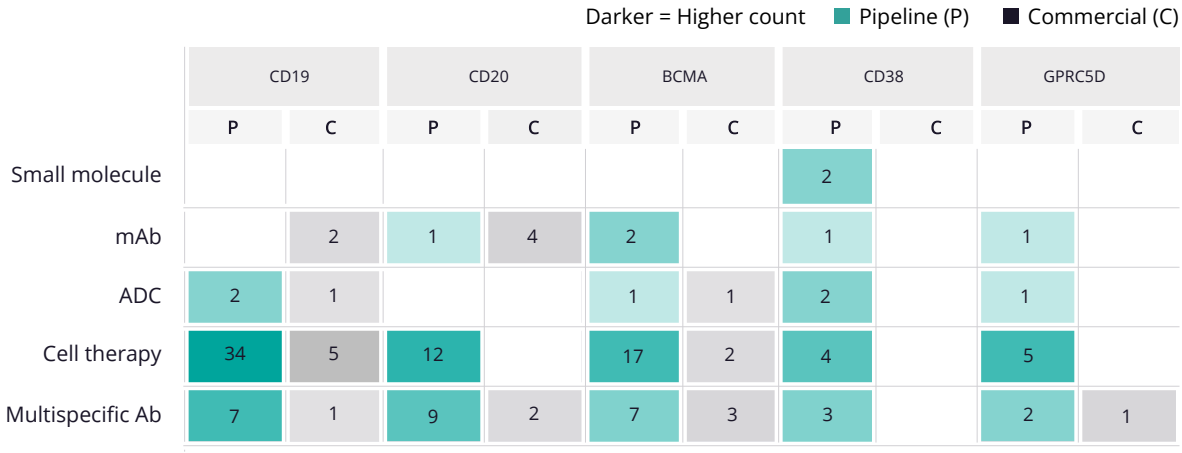
FIGURE 6:

Assets by modality for common extracellular targets



Notes: Pipeline and commercial are shown side by side by target. Zeros are left blank. mAb = Monoclonal antibodies; Ab = Antibodies; RLT = Radioligand therapies.

Sources: ZS analysis, Trialtrove (data extracted in March 2026)



Notes: Pipeline and commercial are shown side by side by target. Zeros are left blank.

Source: ZS analysis, Trialtrove (data extracted in March 2026)

Implications:

Oncology portfolio teams must link target choice and modality choice from the outset. They can no longer treat these as sequential decisions. The ZS Right Opportunity framework and Revelen platform address this derisking problem by combining molecular and genetic evidence with clinical trial data to score target or asset fit with different indications.

Bet on novel modalities, but with a stopwatch

Bispecific ADCs, trispecific antibodies, individualized neoantigen therapies (INTs) and in vivo CAR-Ts (Figures 7a-d) expand the industry's technical toolkit, with emerging pharma and partnerships or acquisitions with established companies driving much of this activity.

Bispecific ADCs and trispecific antibodies combine derisked components—such as targets, payloads and immune engagement strategies—in ways that address acquired resistance or multiple disease pathways. As a result, their average probability of technical and regulatory success (PTRS) matches or exceeds the oncology average. Developers still need to manage potentially additive toxicities and the risk that tumors develop resistance to multiple targets within a single therapy.

INTs and in vivo CAR-T use newer approaches and their average PTRS trails the oncology average. Even so, in vivo CAR-T candidate KLN-1010 showed strong early efficacy data from the phase 1 inMMyCAR trial presented at ASCO 2026.

Novel oncology modalities

FIGURE 7a

Evolution of bispecific ADCs and bispecific ADC targets

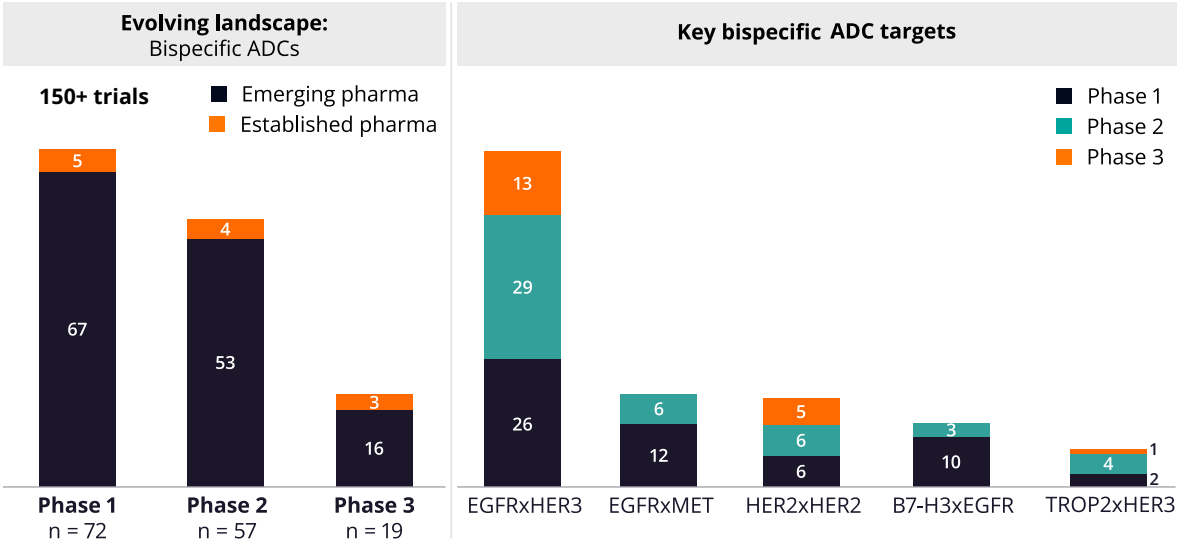
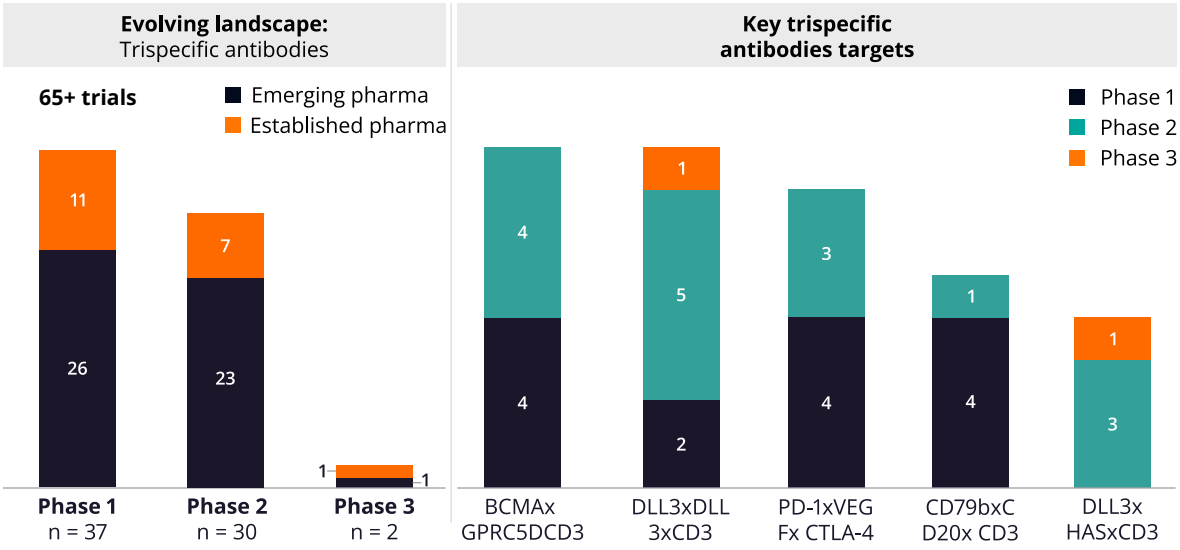


FIGURE 7b

Trispecific antibody targets and trials



Note: Established pharma includes top 20 companies in oncology based on 2025 revenue.

Sources: ZS analysis, Trialtrove and PharmaProject (data extracted in March 2026)

Implications:

Companies should adopt a fail-fast philosophy with clear decision gates for novel modalities or higher-uncertainty development situations. To achieve that, leaders must:

- Deeply understand disease biology and drug metabolism to optimally link disease to drug.

- Optimize for therapeutic index and deprioritize programs with unmanageable safety signals.
- Define treatment duration, such as fixed versus to progression, upfront.
- Predicate advancement of assets on signals of efficacy in relevant endpoints that translate to registration-enabling endpoints.

FIGURE 7c

In vivo CAR-T development landscape

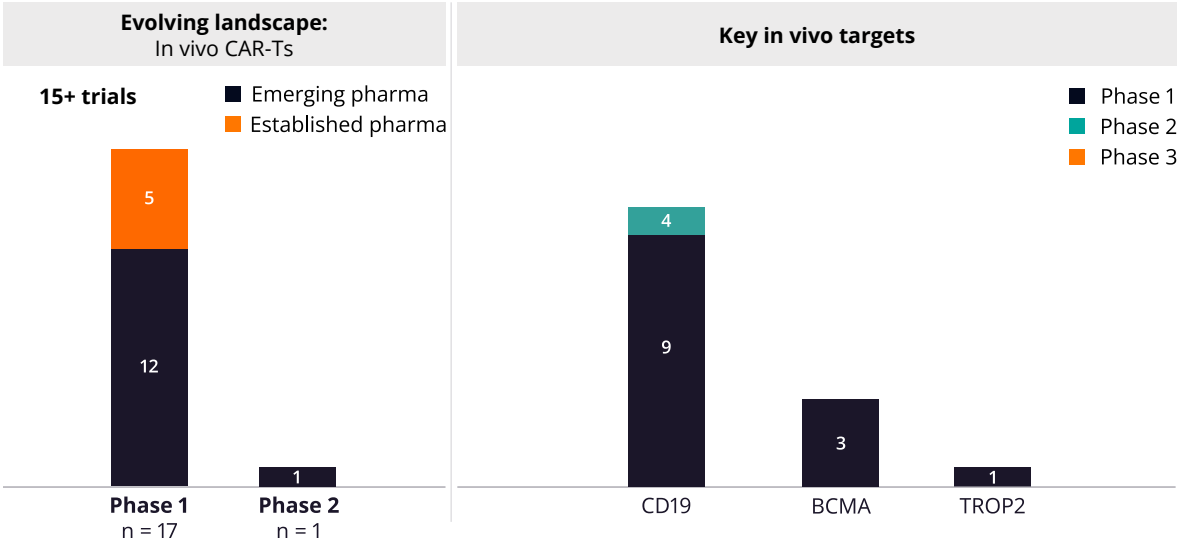
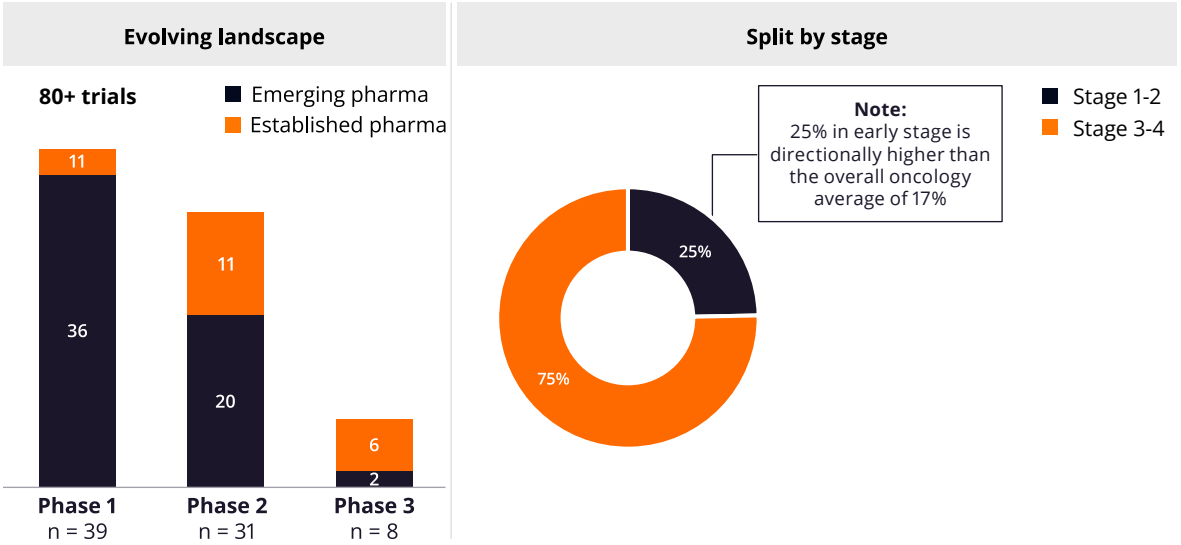


FIGURE 7d

Individualized neoantigen therapies



Note: Established pharma includes top 20 companies in oncology based on 2025 revenue.

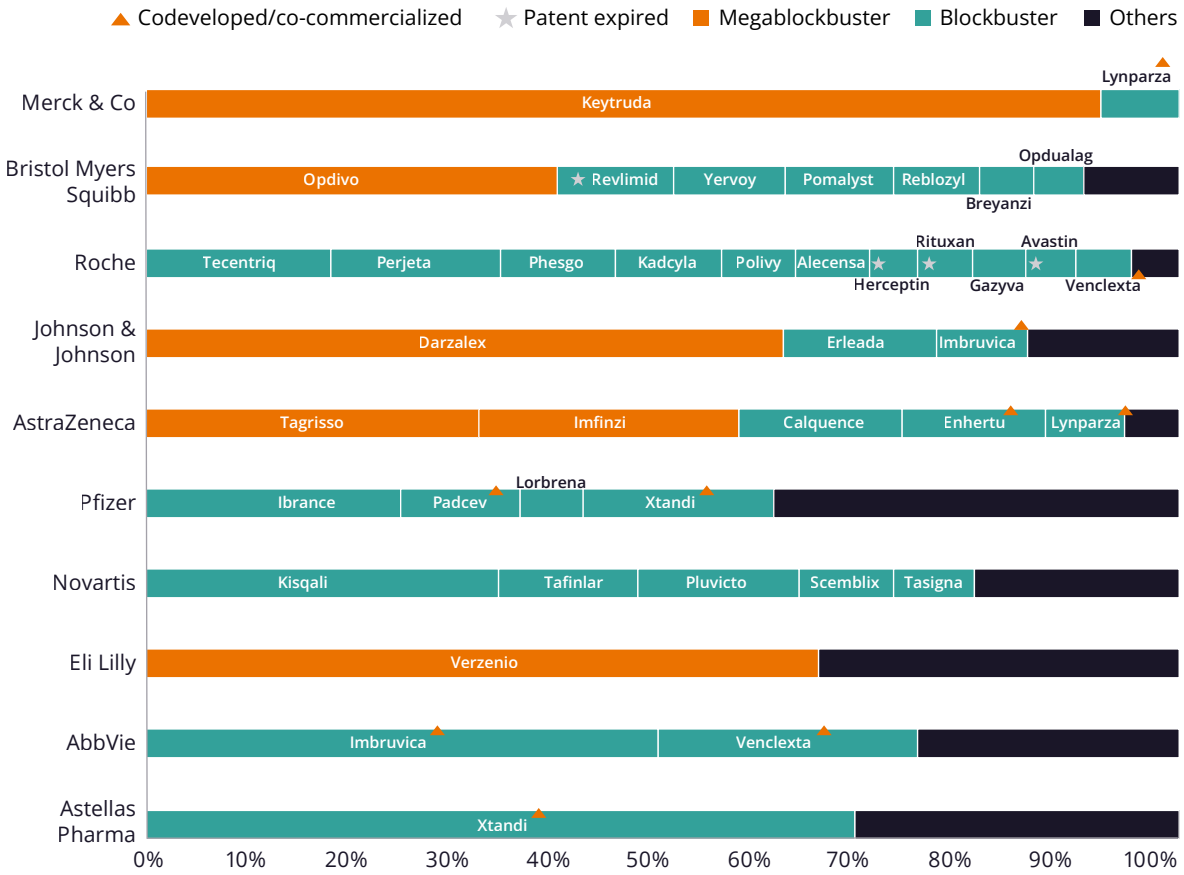
Sources: ZS analysis, Trialtrove and PharmaProject (data extracted in March 2026)

Plan development of potential blockbusters proactively to mitigate the impact of loss of exclusivity events

As illustrated in Figure 8, across the top 10 oncology companies, blockbusters and megablockbusters anchor portfolios. There is room for variability in portfolio composition beyond that—Merck's oncology portfolio sales are almost entirely from Keytruda, for example—while Genentech and Novartis have multiple smaller blockbuster and nonblockbuster medicines.

FIGURE 8

Oncology portfolio composition for top 10 oncology companies by 2025 sales



Notes: Megablockbusters (≥$5B); blockbuster ($1-4.9B); others (<$1B); product revenue contribution reflects its share within a specific company and is not directly comparable across companies.

Sources: ZS analysis, EvaluatePharma (data extracted in March 2026)

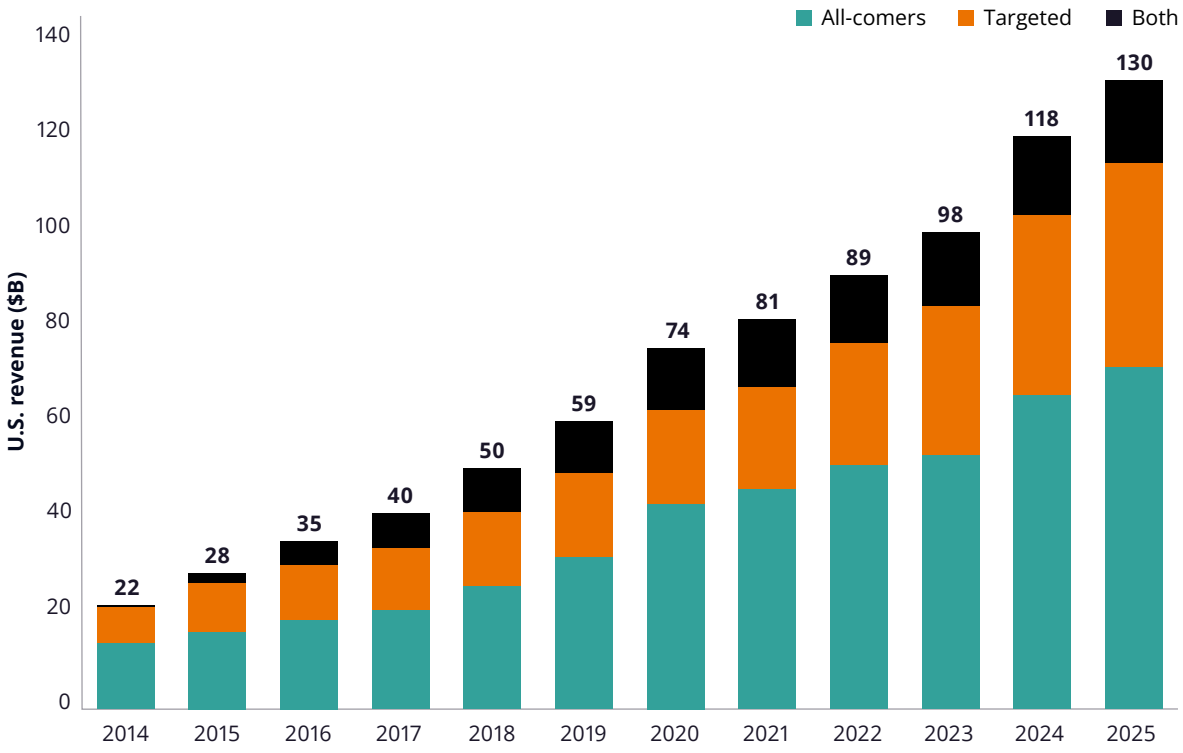
Portfolio concentration around a single product increases the steepness of patent cliffs, making external innovation a strategic necessity when there are no megablockbuster heirs apparent. With Keytruda and Verzenio LOEs on the horizon, Merck and Lilly respectively have been active in alliances, licensure and acquisitions. For example:

- Merck is codeveloping ADCs with DSI, exclusively licensing Kelun-Biotech ADCs outside of China and has acquired Tern Pharmaceuticals. To further reduce commercial risk, Merck is splitting oncology from the rest of its organization.
- Lilly acquired POINT Biopharma for radioligand therapy, Ajax for JAK inhibitors and in vivo CAR-Ts from Kelonia and Orna.

Figure 9 illustrates that while medicines addressing all-comer populations make up most of the U.S. oncology revenue, medicines targeted to specific populations are still a large proportion of revenue. Taken with Figure 8, which shows blockbusters and megablockbusters can be either all-comers or targeted medicines, there is optionality in constructing an oncology portfolio.

FIGURE 9

U.S. oncology revenue by therapy type

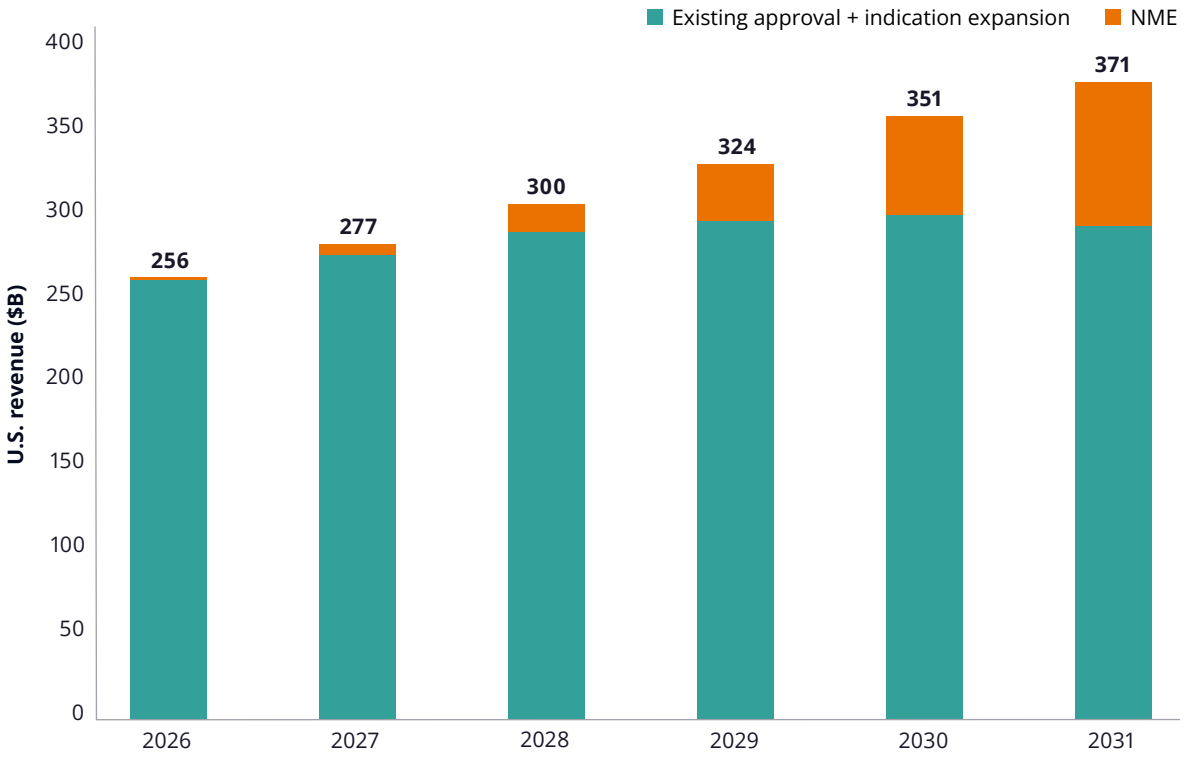


Sources: ZS analysis, EvaluatePharma (data extracted in March 2026)

Over the next five years, indication expansion from medicines already commercially available is expected to drive the majority of oncology revenue (Figure 10). Only from 2030 onward does new molecular entity (NME) revenue become a meaningful proportion of total oncology revenue, indicating that NMEs in aggregate take time to substantially contribute to oncology revenue.

FIGURE 10

Global oncology revenue projections for 2026 onward by NMEs vs. indication expansion



Notes: Existing approval + indication expansion includes products launched prior to Jan. 1, 2026; NME includes novel products launched after Jan. 1, 2026.

Sources: ZS analysis, EvaluatePharma (data extracted March 2026)

Implications:

Oncology companies need blockbusters and megablockbusters to anchor their portfolios, but must also consider three factors:

- Concentration around a few products, or a single product, increases LOE risk.
- Medicines that address all-comer populations can be blockbusters, as can medicines that address targeted populations.
- The next generation of oncology portfolio NMEs should launch three to five years in advance of major LOEs to meaningfully offset revenue lost to LOE.

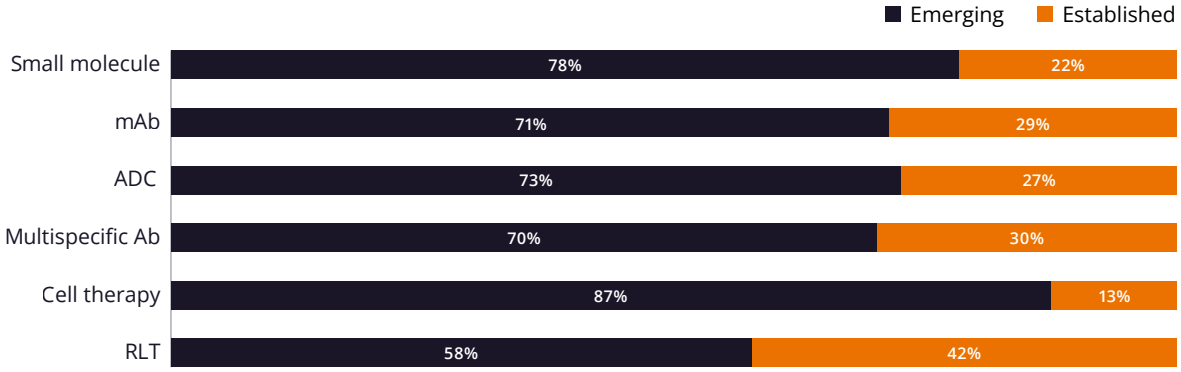
Prioritize platform-centric external innovation from emerging pharma

Emerging pharma now drives the majority of oncology clinical trials across most modalities (Figure 11a). China, in particular, has evolved into an oncology innovation engine (Figure 11b), driven by scientific sophistication, faster trial timelines and lower per-patient costs than the U.S. This was underscored at ASCO 2026 in data showing medicines originating in China accounted for 25% of late-breaking abstracts, including Akeso's HARMONi-6 trial presented in the plenary.

Development and sourcing of external innovation

FIGURE 11a

Percentage of global clinical trials for different modalities by established vs. emerging pharma

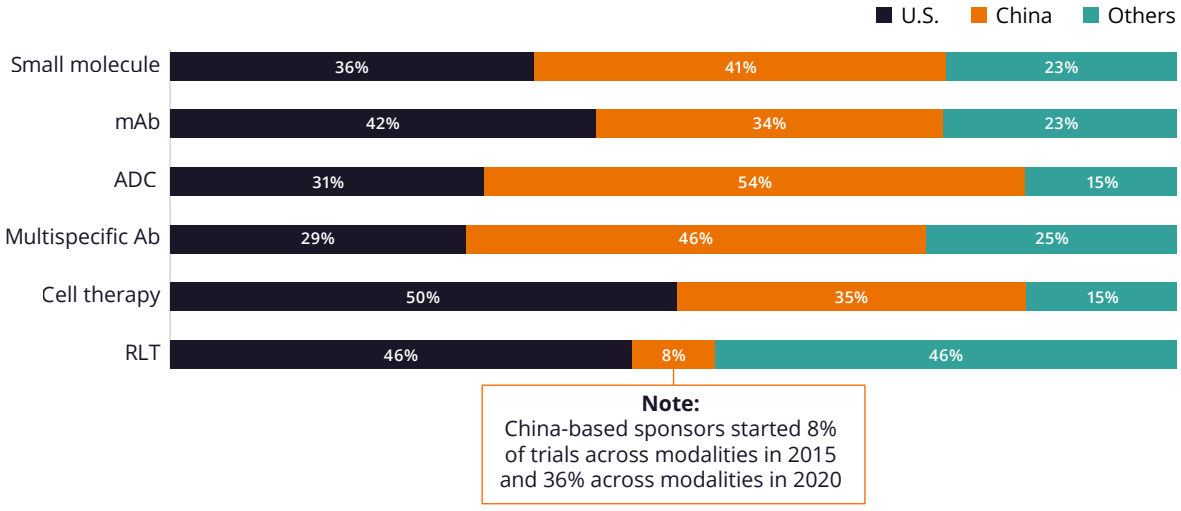


Notes: Ongoing trials in multiple modalities have been counted separately for each modality. Established pharma includes top 10 oncology companies by worldwide 2025 revenue. Clinical trial evaluated by both established and emerging pharma have been counted in both categories.

Sources: ZS analysis, Intelligencia (including all ongoing trials; data extracted in April 2026)

FIGURE 11b

Percentage of global clinical trials for different modalities by sponsor location



Notes: Ongoing trials in multiple modalities have been counted separately for each modality. Percentages may not equal 100% due to rounding.

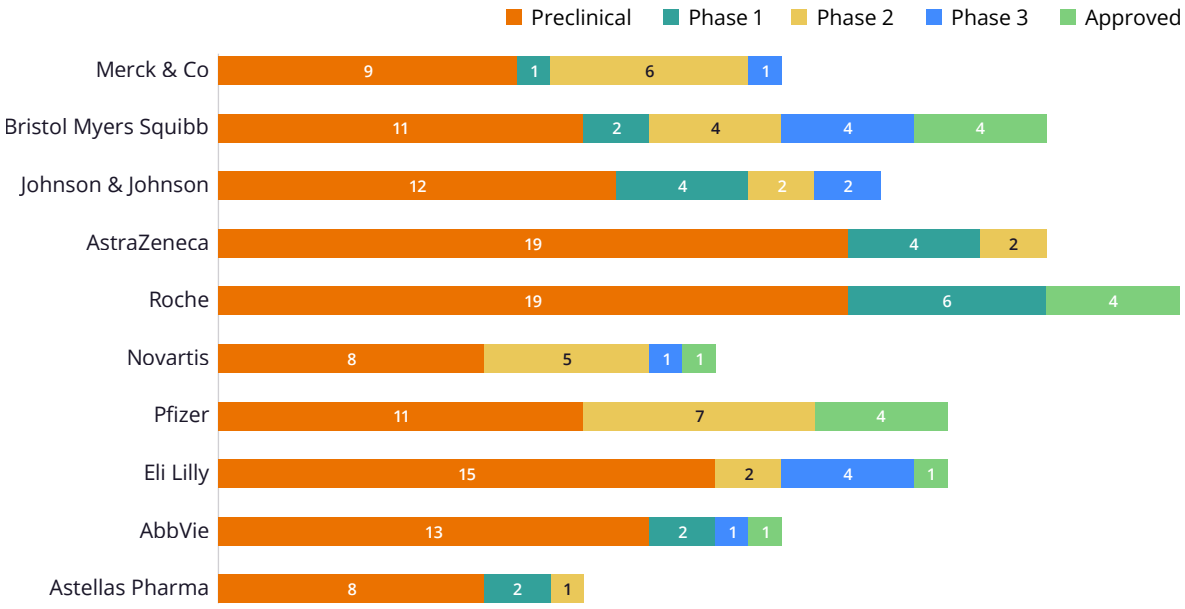
Sources: ZS analysis, Intelligencia (Including all ongoing trials; data extracted in April 2026)

We also observe established companies increasingly accessing external innovation through:

- Preclinical and early phase licensing (Figures 11c-d)
- Platform-centric licensing deals (Figure 11d)

FIGURE 11c

Global oncology deals by development stage, 2021-2025, for top 10 companies by 2025 oncology revenue

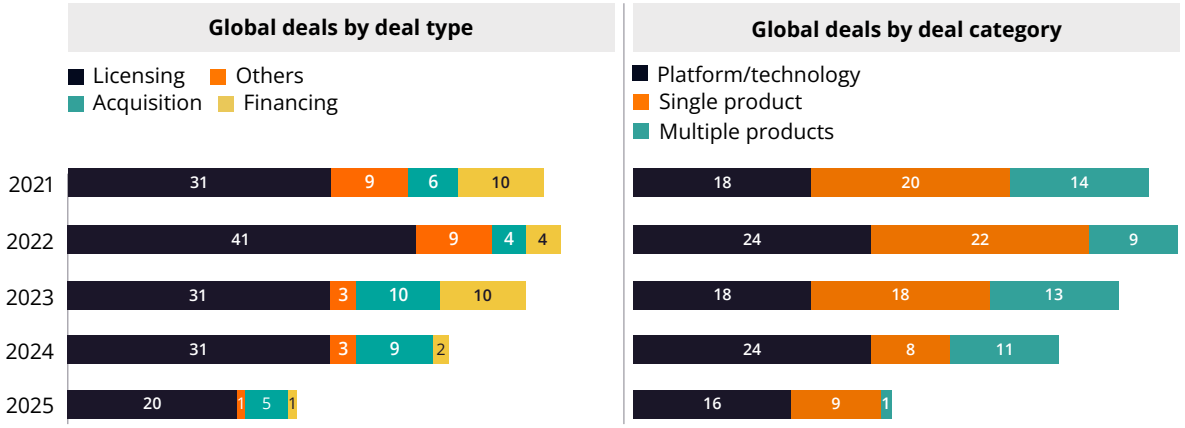


Notes: Top 10 oncology companies based on 2025 global revenue.

Sources: ZS analysis, BiomedTracker (data extracted in March 2026)

FIGURE 11d

Composition of oncology deals from 2021-2025 for top 10 companies by 2025 oncology revenue



Notes: Top 10 oncology companies based on 2025 global revenue. Deals without explicit details excluded from analysis; licensing deals are included as a key deal characteristic under the alliance deal type. Platform/technology defined as platform or technology (e.g. uSMITE platform) deal.

Implications:

External sourcing must become structured and repeatable, not solely opportunistic. In practice, this means companies should build a disciplined external-sourcing playbook with three distinct lanes:

- Seek external innovation from emerging companies focused on specific modalities or targets, including companies based in China. When seeking innovation from China, organizations should work with affiliates and partners for local diligence. Lilly, Pfizer, BMS and Roche are establishing gold standards for this process.
- Use platform-driven modality investments against differentiated targets as long-term portfolio builders.
- Focus opportunistic, later-phase deal-making on near-term revenue shortfalls.

Make clinical trial operations a strategic priority

Although oncology R&D spending has increased over the past decade plus, oncology clinical trial success rate has been declining. Oncology clinical trials also face enrollment and procedure challenges that lengthen timelines relative to nononcology trials. In practice, this shows up in three ways:

- Enrollment success is declining.
- Procedures, endpoints and data points are increasing. ASCO published an article that drove this point home, finding that over 80% of oncology clinical trials undergo at least one protocol amendment.
- Investigator time requirements are growing.

At the same time, clinical trial recruitment has become more competitive, both for less common cancers like glioblastoma multiforme and ovarian cancer, as well as for high-unmet-need cancers like pancreatic, gastric and lung (Figure 12).

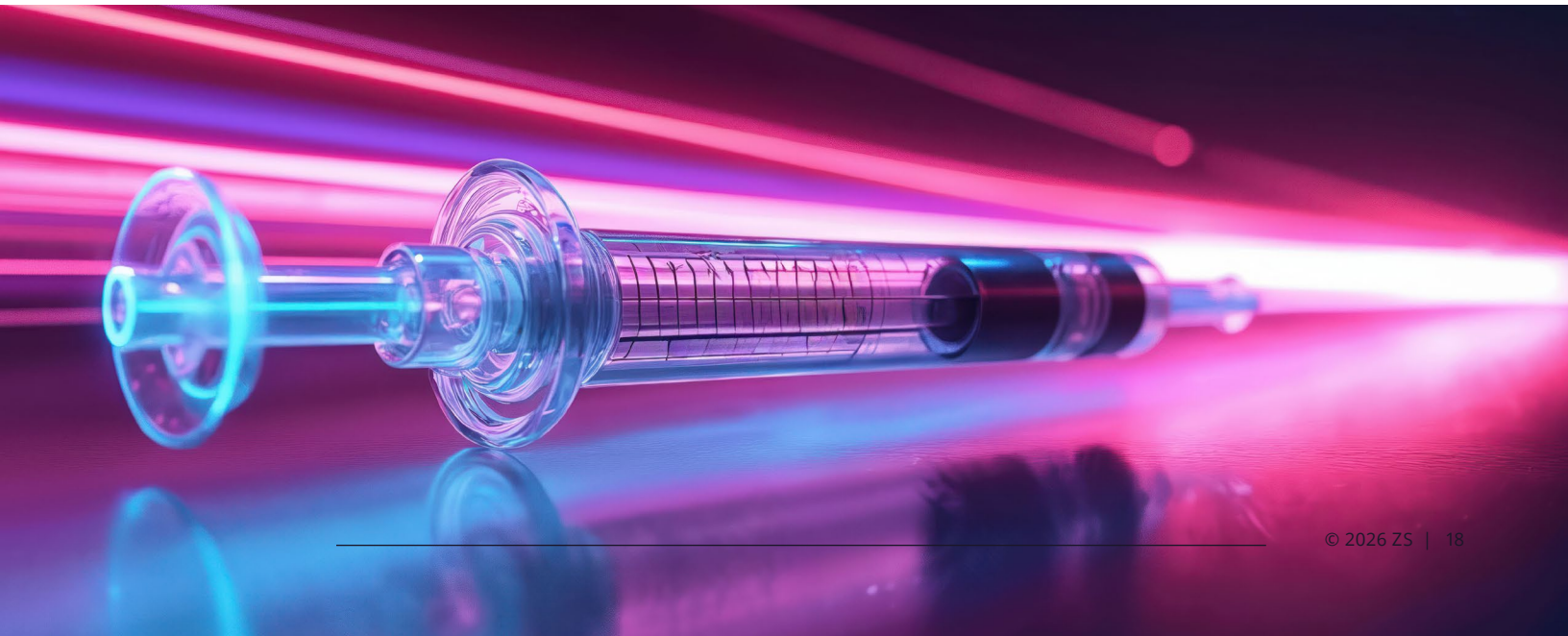
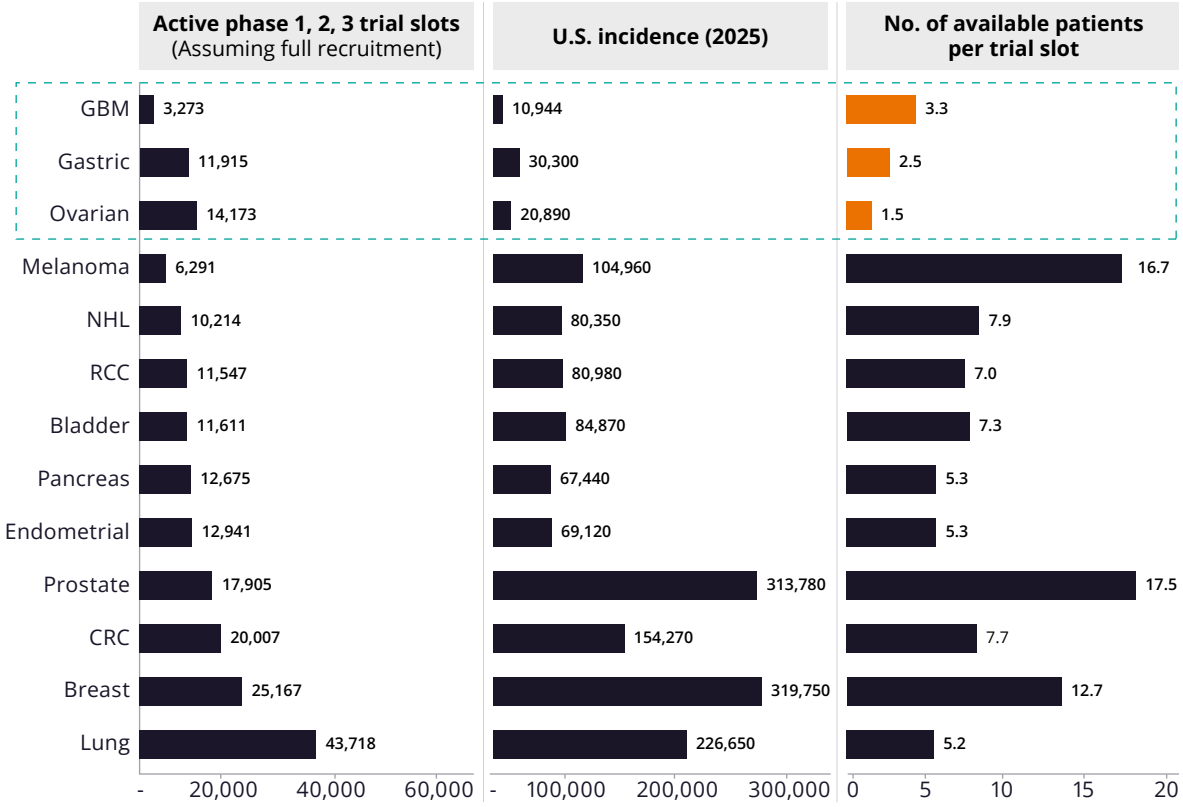


FIGURE 12

Active trial slots compared to U.S. incidence in select tumor types in 2025



Notes: Active patient number may be counted across indications if the trial is for more than one indication (e.g., basket trials). Trials with open status have been considered. GBM = Glioblastoma

Sources: ZS analysis, Trialtrove and US SEER (data extracted in March 2026)

Implications:

The industry needs to understand the experience of patients who are in clinical trials, as well as factors that promote retention. ZS has conducted research with patients in clinical trials through our Patient Experience Bank and found the following:

- Patients want assurance they will get a medicine that works—not a placebo or an outdated standard of care.
- Patients need help with transportation, lodging and meal costs.
- Patients seek continuity of care in terms of their site and managing oncologist.

The industry also needs better solutions in four areas:

- Pressure-testing trial parameters with in silico trials before launching physical trials.
- Selecting clinical trial sites analytically, based on addressable patient population, clinic infrastructure and past enrollment success.

- Forecasting clinical trial enrollment to more precisely understand timelines and costs.
- Accelerating protocol digitization, optimization and authoring with AI.

How can global oncology companies enable success for regions and affiliates?

Regional and affiliate success now depends on bringing local market realities into portfolio strategy much earlier. Differences in cancer burden, evidence expectations, pricing exposure and regulatory timing can materially change where an asset should launch, how it should be sequenced and what support affiliates need.

Companies that treat these considerations as downstream commercialization questions risk building plans that work globally in theory but break locally in execution.

Factor variation in global cancer burden into launch sequencing and strategy

Global cancer incidence is approaching 20 million cases per year, and although the U.S. anchors industry economics, it accounts for only 12% of that burden. China and Europe comprise an additional 46%. Cancer profiles across these three geographies are converging. Breast, prostate, lung and colorectal cancer are the most common tumor types across all three regions.

Cancer is not a global monolith, however. For example:

- Gastrointestinal (gastric, liver and esophageal) cancer incidence and mortality burden is disproportionately higher in the APAC region compared to the U.S.
- Cervical cancer incidence is nearly seven times higher in Sub-Saharan Africa than in higher-income countries.
- Higher proportions of never-smokers in East Asia are diagnosed with lung cancer compared to the U.S.
- ASCO 2026 expanded upon these variations and disparities in the ASCO educational book “Global Oncology: Tackling Disparities and Promoting Innovations in Low- and Middle-Income Countries,” published alongside the conference.

Implications:

Global oncology development and commercialization must reflect regional disease biology, risk factors and healthcare infrastructure realities. This requires close collaboration with affiliates to understand regional cancer burden implications for portfolio prioritization, such as bringing gastrointestinal cancer assets to APAC earlier in the launch sequence.

Shift pricing strategy earlier in clinical development and bring affiliates together to consider pricing strategy interplay

In May 2025, U.S. President Donald Trump signed the Most Favored Nation (MFN) executive order, which sought to lower U.S. drug costs through international reference pricing. At the time, oncology medicine list prices in high-income countries averaged 54% lower than in the U.S.

Since the policy's introduction, more than 15 established pharmaceutical companies have entered MFN agreements with the U.S. government. Although most have oncology portfolios, the impact on oncology medicines has been limited so far.

Tabrecta and Rydapt from Novartis are the only confirmed oncology drugs with negotiated price reductions. However, if more oncology medicines are included in MFN agreements, ASCO has modeled that providers may have to acquire medicines at prices above reimbursement levels. What's more, up to 19% of Medicare patients could lose access to their oncology medicines if providers can no longer afford to purchase and administer them.

Outside the U.S., MFN's impact is already taking shape. Reference European market launches have declined by 43%. In a Q1 earnings call, Novartis CEO Vas Narasimhan noted that, "Depending on how you look, 30% to 40% of medicines … available in the U.S. don't ultimately come to Europe." This is one indication that withdrawal from or nonlaunch in reference markets is a real possibility.

This sentiment was echoed by AstraZeneca CEO Pascal Soriot as an MFN worst-case scenario for its impact on its business. Additional research has shown that MFN carries a risk of incentivizing deprioritization of lower-price geographies, a risk underscored in a recent ASCO article.

Some leaders are more optimistic. In January 2026, David Fredrickson, AstraZeneca's executive VP of oncology, said as more companies enter MFN agreements, there is "an opportunity for there to be some real scale and inertia behind increasing the funding for innovation across the globe in a more balanced way."

Implications:

Oncology medicines are essential and patients globally must be able to access them. To help balance this imperative with preserving portfolio value, companies must:

- Integrate pricing strategy and intended launch sequencing earlier in clinical development.
- Re-evaluate the role of value-based pricing.
- Consider U.S. price, EU price and launch timing as a single, integrated system.
- Integrate pricing risk modeling into indication prioritization, biomarker strategy and registrational endpoint selection.

The leadership question now is whether your pricing, indication strategy and launch sequence are being decided in the same room.

Ensure that regulatory has strong input to launch priority and sequencing

The U.S. Food and Drug Administration (FDA) has deployed many programs in the last several years aimed at both raising the bar for evidence in submissions and accelerating patient access to novel medicines.

Examples of programs targeting evidence submissions include:

- **Through 2026:** Increasing complete response letters (CRLs), which reflects increased rigor around chemistry, manufacturing and controls, as well as increasing transparency around the rationale for CRLs.
- **Through 2026:** Increasing rigor around requiring active comparators (even for CAR-T) and selecting appropriate comparators, such as Oncologic Drug Advisory Committee (ODAC) feedback on the SERENA-6 trial.
- **Through 2026:** Issuing guidance to sponsors to design trials that are not only globally efficient but also demonstrably reflective of real-world U.S. patients, including in ODAC feedback on the STARGLO trial.
- **2024:** Guidance from ODAC to separate out perioperative trials into distinct neoadjuvant and adjuvant trials. Notably, data presented at an ASCO 2026 plenary included LIBRETTO-432, which was a purely adjuvant trial.
- **2024:** Providing FDA guidance through Project Optimus involving a push toward improved dose optimization—rather than maximization—and selection to balance efficacy and safety.
- **2021:** FDA's Project Confirm program mandates greater urgency around confirmatory trial initiation for medicines receiving conditional or accelerated approval.

When it comes to accelerating patient access to novel medicines, federal actions include:

- **2026:** Starting an early-stage clinical trial pilot to reduce development timelines by six to 12 months to bridge the gap with China's drug development timelines.
- **2026:** Launching a clinical trial pilot allowing drug sponsors to submit data to the FDA in real time to accelerate drug development and regulatory decision-making. AstraZeneca (phase 2 TRAVERSE trial for mantle cell lymphoma) and Amgen (phase 1b STREAM-SCLC trial for SCLC) are piloting this program.
- **2026:** Releasing draft guidance indicating a shift in multiple myeloma trial expectations, allowing minimal residual disease negativity and complete response as primary endpoints for accelerated approval.
- **2025:** Starting the Commissioner's National Priority Voucher pilot program to dramatically reduce review times for selected medicines.

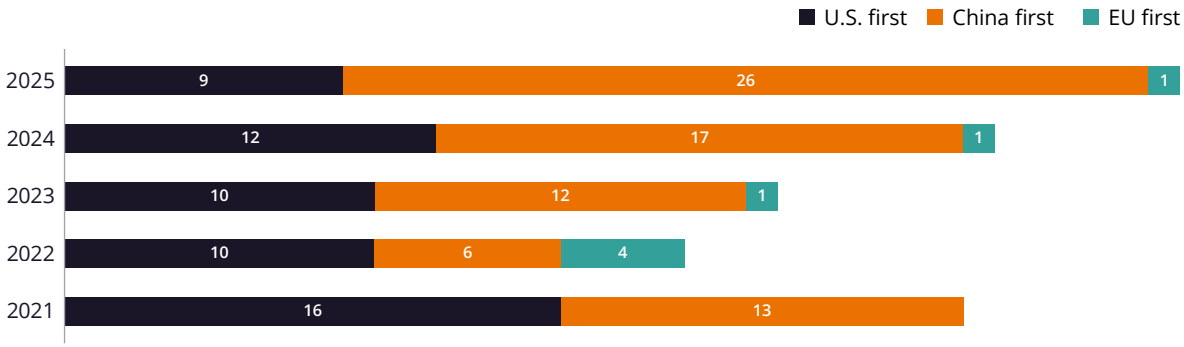
The confluence of these programs can make approval timing challenging to predict.

As the U.S. regulatory market evolves, China's expanding role in oncology innovation is becoming harder for global portfolio teams to ignore. China has outpaced the U.S. in oncology first-in-world approvals, as shown in Figure 13.

However, U.S.-first approvals show broader global expansion after launch—71% expanded to other countries after U.S. launch, while China-first launches remain largely domestic, with 7% launched outside of China.

FIGURE 13

Number of first-in-world oncology drug approvals in the U.S., China and Europe between 2021-2025



Note: U.S. first, China first and EU first indicate the region of initial approval. All data is mapped to the first launch region.

Sources: ZS analysis, FDA, EMA, Global Forum

Implications:

Global organizations must work closely with affiliates and with regulatory to:

- Understand the effect of the latest regulatory policy on clinical development timelines and continuously update launch readiness timing as policy shifts.
- Stage gate commercial investment by region if a U.S. launch is not feasible due to a lack of U.S. data, or an EU launch is not feasible due to evidence requirements.
- Optimize launch sequence and timing, including cases where the EU should launch ahead of the U.S., as with sugemalimab or the glofitamab STARGLO regimen.

Global oncology business unit leaders must decide where oncology growth should come from across markets and how to build portfolios, evidence strategies and affiliate capabilities that can travel. That means making clearer choices about disease-area prioritization, portfolio construction and the role regions and affiliates play in adapting strategy to market realities.

Global oncology leadership teams now need to ask themselves the following questions:

1. Where is your portfolio optimizing? In which cancers and which stages of disease?
2. How is your portfolio differentiated today? What about in five years?
3. What is the most impactful action you have taken to establish better collaboration with affiliates?

Strategic outlook for U.S. oncology leaders

Three questions sit at the top of every U.S. oncology business unit leader's agenda—and they are becoming harder to control as access constraints, care-delivery friction, policy change and competition reshape the market. Those questions are:

- How do we better prepare for launches?
- How can we drive growth with inline brands amid structural headwinds?
- How can we protect value as brands approach LOE?

In this chapter of our report, we will articulate our point of view on each of these essential questions.

How can U.S. oncology leaders better prepare for launches?

A single launch playbook is no longer sufficient in the U.S. With the volume and complexity of oncology launches increasing, organizations must tailor their approach and resource allocation to the specific characteristics of each asset and indication. The most successful launches will not simply introduce a medicine to the market; they will address barriers across the patient journey, support oncology practices in delivering care more efficiently and create value beyond the product itself.

Understand their launch archetype and tailor resources to it

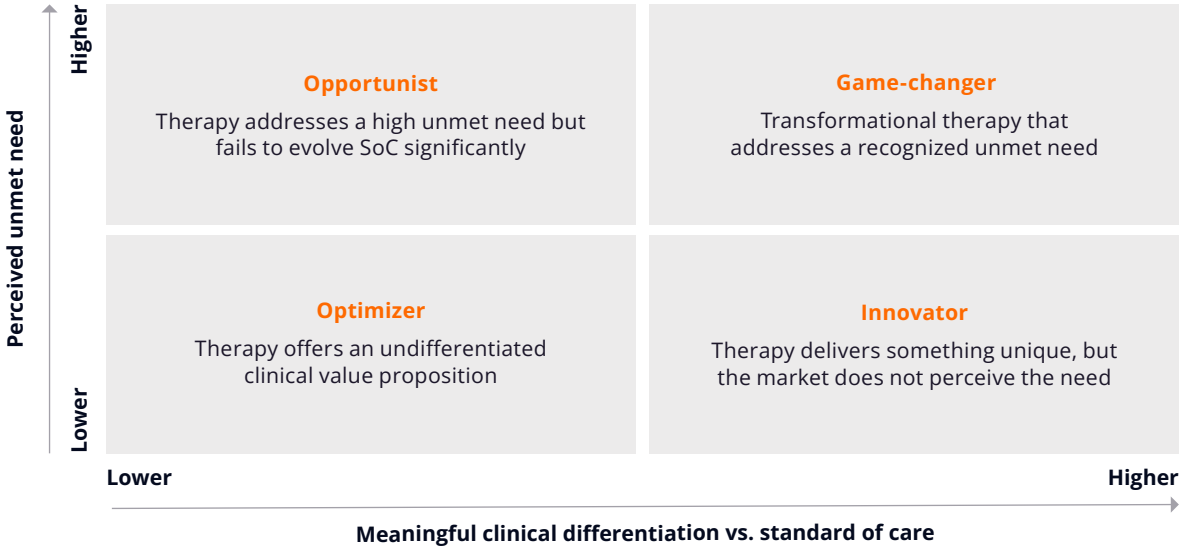
One of the most consequential decisions leading up to and during a U.S. oncology launch is being honest about what kind of launch you actually have. ZS research on launch performance drivers (unmet need, order of entry, efficacy, safety, convenience, novelty and promotional investment) has shown that many launches are inaccurately categorized and, accordingly, risk misallocating resources.

This research showed that for products addressing high-unmet-need indications and offering high efficacy, performance isn't driven as much by promotional investment. By contrast, more competitive and/or lower unmet need spaces required greater promotional investment to secure share of voice. That distinction matters because oncology launch investment should be matched to the asset's actual barriers.

Accordingly, ZS research has also shown that pharma launches can be classified according to perceived unmet need and clinical differentiation versus standard of care (Figure 14 below).

FIGURE 14

Launch archetype diagnostic



Source: "Moving beyond first in class, best in class" ZS white paper

This classification creates four archetypes, each with different implications for launch investment:

- **Game-changer assets** (often first- or best-in-class like Keytruda, Darzalex, etc.) tend to be less promotionally-sensitive, but given that they are often first-in-class, they may require cross-functional engagement in the launch. This sounds simple, but the trap is that many teams misdiagnose themselves as being in this archetype when they are not.
- **Innovator assets** (delivering a unique clinical value proposition, but in a lower unmet need space like supportive care) require greater promotional investment (especially in terms of market shaping), with strong support from medical affairs.
- **Optimizer assets** (limited clinical differentiation or low unmet need, attempting to differentiate on non-clinical factors like price) may not see high ROI from heavy or broad promotion, but rather benefit from targeted engagement with the most impactful stakeholders (e.g., payers for a cost-differentiated launch). This also sounds simple, but companies may be hesitant to commit to this strategy unless there is a very clear cost-based rationale.
- **Opportunist assets** (addressing high unmet need, but with limited clinical differentiation like re-formulations of generic chemotherapies) are more promotionally sensitive, especially in terms of field commercial investment.

Company context further modulates these archetypes:

- Company scale and resources may place a "ceiling" on the level of investment.
- By contrast, the existing presence in oncology and ability to leverage infrastructure, personnel and relationships raises the "floor" of investment that is possible.
- Ambition in oncology might drive increased investment regardless of archetype.

Implications:

With launch volume rising and pressure increasing on selling, general and administrative expenses, launch archetype misdiagnosis widens the delta between forecast and actual launch performance. Honest archetyping is a non-negotiable part of launch planning. The companies that keep resourcing every launch to the same intensity will overspend on optimizers at the expense of more promotionally-sensitive archetypes. The companies that treat archetyping as a rigorous, evidence-based diagnosis will resource appropriately and optimize each of their launches.

Understand the factors that contribute to launch under- and overperformance compared to forecast and tailor their launch strategy accordingly

The U.S. carries a disproportionate share of every oncology forecast and disproportionate downside if a launch underperforms. Accordingly, oncology organizations pay deep attention to drivers and barriers of launch performance like indication characteristics, product characteristics, access environment and commercial investment. ZS analysis of factors influencing launch performance has shown a striking divergence. First launch overperformance is driven overwhelmingly by product novelty.

Underperformance, by contrast, is driven by these four predictable factors.

- Lack of clinical differentiation
- Challenging administration protocols
- Payer restrictions
- High price relative to perceived clinical benefit

Implications:

For any first launch that is not genuinely novel, launch teams must critically evaluate which factors may risk driving underperformance. Teams that build their launch plans to mitigate underperformance factors will consistently outperform teams still writing plans as if novelty were on their side.

Commit to the healthcare ecosystem beyond the medicine

While clinical differentiation is correlated with launch success, it is not enough on its own to guarantee launch success. ZS research in 2025 showed that one-third of clinically differentiated launches failed to meet expectations due to commercialization shortcomings. A typical launch faces 50-plus separate barriers. That same ZS research found that only 20% to 30% of launch team effort concentrated on barriers to the patient getting their medicine after the treatment decision.

When manufacturers committed, however, with sustained organizational investment in barrier removal, patient support architecture and access infrastructure, 67% of launches overperformed expectations.

This commitment to barrier removal can also manifest through external partnerships with the healthcare ecosystem to enable better care delivery, for example:

- AstraZeneca provided a medical educational grant to support publication and dissemination of best practices around multidisciplinary teams (MDTs) in cancer care, emphasizing coordination between oncology, pathology, radiology and molecular diagnostics.
- Genentech partnered with OneOncology to improve biomarker testing uptake across community practices and help healthcare professionals (HCPs) interpret NGS results.
- Johnson & Johnson partnered with HCA Healthcare to improve early detection of lung cancer in the Black community.

Implications:

Clinical differentiation is no longer enough. Manufacturers must demonstrate commitment to the full patient journey by:

- Adopting a barriers-driven engagement™ model to understand where and when to make the most impact for each customer
- Investing in commercial models that support patients past the treatment decision, into access, fulfillment and adherence
- Partnering with the healthcare ecosystem through efforts such as MDT enablement and community access to precision medicine to improve outcomes for patients with cancer

How can U.S. oncology leaders drive growth with inline brands amid structural headwinds?

Inline brand growth in the U.S. will depend on whether companies can keep improving uptake and outcomes after launch, even as structural barriers intensify. For business unit leaders, the challenge is no longer simply defending share or expanding use; it is identifying where access, affordability, care-delivery capacity and oncologist workflow friction are limiting the real-world impact of their medicines. Growth will come from brands that help close those gaps while adapting investment to the policy and competitive pressures reshaping the inline revenue window.

Identify the impact of structural barriers on your brands and lead the coalitions to address them

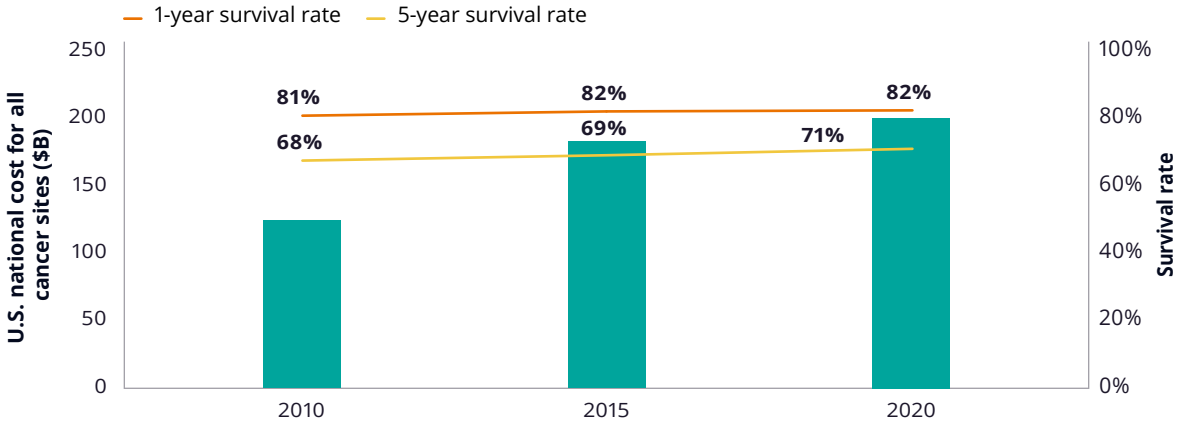
Despite improvements in survival across most cancers since the 1970s, improvements in cancer outcomes are not equitably distributed, for example:

- Rural mortality rates are 21% higher than urban rates, with particular disparities in lung (45%) and cervical (36%) cancers.
- There are significant disparities by race, especially for prostate cancer and multiple myeloma among Black men and breast and endometrial cancers among Black women (National Cancer Institute).

While cancer survival has improved markedly since the 1970s, improvements have started to slow over the last 10-plus years, despite U.S. oncology spend rising over 60% in the same time period (Figure 15 below). Projections show U.S. oncology spend increasing to $245 billion by 2030, further exacerbating this disconnect.

FIGURE 15

U.S. oncology spend and survival rates (2010, 2015, 2020)



Note: National cost projections include medical services (Medicare Part A and B) and oral prescription drugs (Part D).

Sources: "Cancer in Medicare: An ACS CAN Chartbook" and SEER

Outcomes are stagnating in the U.S. despite incredible innovation in cancer treatment because of structural, health system-level constraints:

- **Access and affordability:** Compared to privately insured patients, uninsured or Medicaid-insured patients in the U.S. are less likely to receive cancer screening, increasing their chances of later stage diagnosis, leading to worse short-term and long-term survival. Further, Medicare beneficiaries with cancer spent an average of $4,800 out-of-pocket in 2023 compared to $2,364 for beneficiaries without cancer.
- **Capacity for care delivery:** Even within the U.S., 68% of the population lives in counties where oncologist coverage is at risk. Further, for newer, logistically complex treatment modalities like CAR-T, the healthcare system has not been able to treat all eligible patients. With fewer than 200 sites authorized to deliver CAR-T in the U.S., most patients must travel multiple times throughout their journey for evaluation, apheresis, lymphodepletion, CAR-T infusion and monitoring. Accordingly, in the U.S., 65%-75% of patients clinically eligible for CAR-T do not receive CAR-T and 47% of CAR-T providers experience capacity constraints per ZS research in 2025.
- **Oncologist fragmentation and burnout:** A ZS analysis of 19,000 oncologists treating 2.8 million patients from 2019 to 2022 found that 90% of oncologists treat at least nine tumor types, with oncologists practicing in community settings far more fragmented than those practicing in academic settings. This fragmentation contributed to observed lower adoption of novel therapies. Increasing fragmentation and increasing workload overall also contribute to rising oncologist burnout, with 59% of oncologists reporting burnout in 2023, up from 45% in 2013.

Implications:

These structural barriers need AI-powered and coalition solutions that combine industry, academia and government input:

- Across cancers, the industry needs to better understand disparities (within specific geographic catchments, for specific genders or specific ethnicities) by assessing care gaps via patient-level claims and social drivers of health data.
- The industry must also increase access to clinical trials and novel medicines for patient groups experiencing disparities, in part by empowering patients to seek and obtain the healthcare that they need.
- Specifically for more logistically complex treatment modalities like CAR-T, the industry needs to work with the healthcare system and regulators to move the patient journey closer to the patient (e.g., into the community, as outpatient, with less-burdensome monitoring requirements).
- The industry needs to help develop better tools for oncologists to manage increasingly complex care like well-validated and regulated AI clinical decision-support tools to support molecular profiling decisions and treatment planning.

Account for the Inflation Reduction Act (IRA) as a structural headwind compressing inline brand economics

The IRA has moved from a policy debate to a first observable data point in oncology: Imbruvica, the only oncology medicine in the 2026 cohort negotiated by the Centers for Medicare & Medicaid Services (CMS), received a 38% Maximum Fair Price discount, the smallest of the 10 drugs in the cohort (other discounts landed between 50% and 80%).

Even that comparatively favorable outcome came alongside a ~16% year-over-year (Q1 2025 to Q1 2026) drop in worldwide Imbruvica sales, which AbbVie attributed to IRA impact and competition on its Q1 2026 earnings call. Johnson & Johnson primarily cited "rising competitive pressure in the United States due to new oral competition."

For Imbruvica, the impact of IRA appears less like a discount that could be mitigated by increased volume or competitive advantage via pricing and more like a haircut. The mentions of competitive pressure are an important context; the presence of well-positioned "second-generation" Bruton's tyrosine kinase inhibitors (BTKi) make the CMS discount a less appealing driver of choice for new patient starts.

The 2027 oncology cohort (Xtandi, Pomalyst, Ibrance and Calquence) is set for 40%-60% discounts. Part B is not yet in scope, and Keytruda and Opdivo are not eligible until 2029 following recent eligibility revisions. The impact of negotiation on the 2027 cohort will be instructive, as there is a wider range of competitive context and potential competitors entering each market. Calquence in particular as a second-generation, blockbuster BTKi, will be a signal of how well (or not) sales can be protected from IRA impact.

Implications:

As IRA headwinds compress revenue windows, oncology leaders need to reassess commercialization strategy in three ways:

- Quantify brand-level IRA exposure based on modality, time on market, spending through CMS and orphan drug status.
- Bifurcate commercial investment and access strategy to pre- and post-CMS negotiation revenue periods. The post-CMS negotiation period in particular can be thought of as a transition period to the loss of exclusivity.
- Work with global oncology organization partners to ensure that U.S.-specific IRA dynamics are reflected in global life cycle and sequencing decisions (e.g., shifting higher-value indication U.S. launches earlier in the product life cycle).

How can U.S. companies protect value as brands approach LOE?

As oncology brands approach LOE, U.S. leaders need to protect value in ways that go beyond traditional defense. Reformulation, coformulation, contracting and real-world evidence (RWE) can all help extend value, but only when they create a credible benefit for patients, providers or payers. The most effective LOE strategies will therefore start years before exclusivity loss and connect commercial defense to a clearer care-delivery or evidence-based reason for stakeholders to continue choosing the originator brand.

By 2030, about $50 billion in revenue across the top 10 oncology companies (designated by 2024 sales) is expected to face pressure from LOE. Three products—Keytruda, Opdivo and Darzalex—account for over 50% of this revenue.

ZS has observed many strategies aimed at mitigating LOE (detailed in this section), but the truly successful strategies are those that advance care delivery while extending value.

Evaluate the value proposition of reformulating the originator molecule

ZS research has shown that conversion of intravenous (IV) medicines to subcutaneous (sub-Q) formulations has a wide range of outcomes, summarized in Table 1 on the next page. The pattern suggests that reformulation works best when it solves a meaningful care-delivery problem, not when it is treated only as a revenue-defense tactic. Darzalex to Darzalex Faspro (91% conversion of daratumumab molecule share by 2024) has been highly successful, and Perjeta to Phesgo (29% conversion of pertuzumab molecule share by 2024) has been relatively successful. By contrast, attempts to convert IV Rituxan and Herceptin to sub-Q formulations have been less successful (conversion of 6% and 4% molecule share as of 2024, respectively).

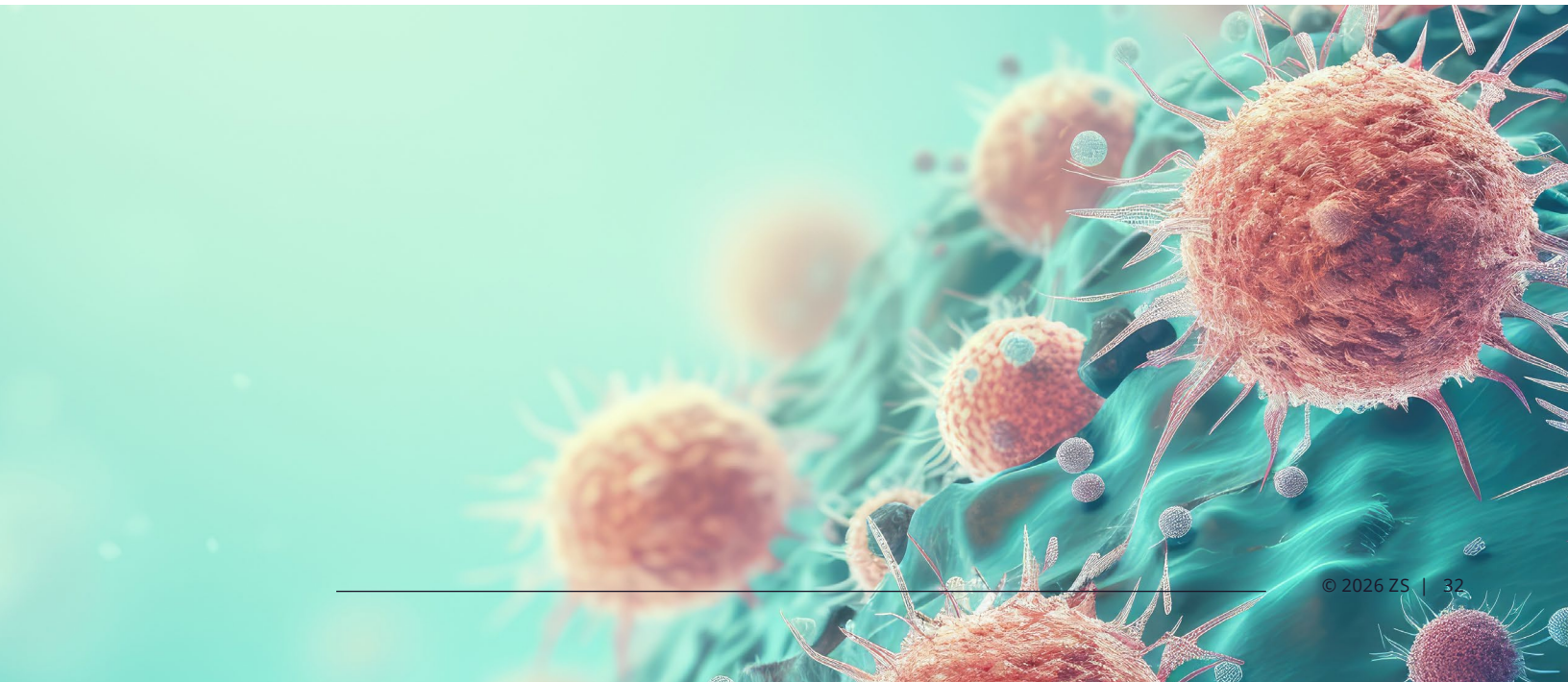


TABLE 1

Previous IV to sub-Q reformulations in oncology

	Rituxan Hycela	Herceptin Hylecta	Phesgo	Darzalex Faspro
Peak IV to sub-Q conversion (% of patients on the molecule)[1]	13% (before biosimilar entry, declined to 6% as of 2024)	4%% (as of 2024)	29% (of pertuzumab molecule share, as of 2024)	91% (as of 2024)
Clinical value proposition	Comparable efficacy and tolerability with exception of local cutaneous reactions with Rituxan Hycela[2]	Comparable efficacy and tolerability[3]	Comparable efficacy and tolerability[4]	Comparable efficacy and tolerability, Faspro superior to Darzalex on rate of infusion-related reactions[5]
Administration value proposition	5- to 7-minute injection vs. 90-minute infusion[6]	2- to 5-minute injection vs. 30- to 90-minute infusion[7]	5- to 8-minute injection vs. 150-minute (60 min + 90 min) total infusion time[8]	3- to 5-minute injection vs. 3 to 4-hour infusion[9]
Breadth of IV indications covered	FL, DLBCL, CLL[6] (not B-AL or non-cancer indications)	HER2-overexpressing breast cancer[7] (not gastric cancer)	All[8]	Most[9] (not combinations with VTd, Kd, Pd)
Timing of sub-Q launch relative to IV LOE	LOE-1	LOE	LOE-5	LOE-9
Biosimilar competition	Yes	Yes	No	No

References:

1. Calculated from data derived from The Komodo Healthcare Map®, which is derived primarily from claims data, accessed through the Prism platform.
2. Rituxan Hycela clinical development.
3. Herceptin Hylecta safety.
4. Phesgo clinical trial results.
5. Darzalex clinical results.
6. Rituxan Hycela dosing.
7. Herceptin Hylecta home page.
8. Phesgo HCP overview.
9. Darzalex Faspro prescribing information.

Using this strategy primarily as LOE defense without incremental value to patients appears unsuccessful. Rituxan and Herceptin sub-Q formulations launched close to IV brand LOE with a positive but not dramatic change in administration time. The sub-Q formulations also didn't cover all the indications covered by the original IV formulation.

By contrast, Darzalex Faspro and Phesgo have a more compelling administration value proposition in terms of chair time saved and also most or all of their IV counterparts' indications. Darzalex Faspro even has a clinical advantage over Darzalex in the rate of infusion-related reactions.

Implications:

If manufacturers want to deliver value to patients while mitigating LOE via reformulation, they need to:

- Select IV medicines with a strong value proposition for sub-Q reformulation (i.e., ability to drastically reduce chair time and improve patient quality of life). The oral equivalent of this is extended-release formulations like Jakafi XR, which reduces the number of pills needed per day.
- Maximize the eligible patient population for the sub-Q reformulation in terms of breadth of IV indications covered.
- Demonstrate clinical parity between sub-Q and IV formulations, ideally with a directional tolerability advantage for sub-Q.
- Launch the sub-Q reformulation well before IV LOE or biosimilar availability. Invest promotionally in the sub-Q reformulation to drive IV to sub-Q conversion (of both continuing and new patients).

Evaluate (with healthy skepticism) the value of novel coformulations

Novel coformulations building on valuable originator molecules to establish best-in-class combinations is a compelling idea in theory: Patients benefit from improved efficacy and the originator molecule's revenue is transferred to the novel coformulation. In practice, however, this strategy faces developmental and commercial hurdles:

- Designing a coformulation that will be more effective than a valuable originator molecule is a high bar to beat; Merck alone shelved three programs attempting to coformulate pembrolizumab with anti-TIGIT, anti-CTLA-4, and anti-LAG-3 molecules for futility.
- Coformulations that are developed successfully may still face competition. Phesgo competes with branded Perjeta and biosimilar trastuzumab, while Opdualag competes in a melanoma landscape fragmented by Opdivo + Yervoy, checkpoint inhibitor monotherapy and several options targeting actionable genomic alterations.

Accordingly, returns from this strategy have been variable:

- Phesgo is a success story, with >$2.5B in sales in 2025. Notably, Phesgo offers patient benefit in terms of substantially reduced chair time relative to Herceptin and Perjeta administered separately.
- Opdualag reached blockbuster status (>$1B) in 2025, but its ceiling is limited by failures to displace Opdivo outside of melanoma.
- Vyxeos sales have held steady in the $100M-$150M range for the last 5-plus years, limited by indication size and perceived value proposition compared to generic 7+3 chemotherapy.

Implications:

Companies should deploy this strategy selectively:

- Coformulating two medicines with the same route of administration in a way that benefits patients (like Phesgo) is a natural fit.
- For combinations (including coformulations) involving novel medicines, previous ZS research on immune checkpoint inhibitor combination development has shown that combinations where both partners have monotherapy efficacy are five times more likely to be successful than combinations where one of the partners does not have monotherapy efficacy.

Explore contracting as a way to improve value compared to generic or biosimilar competition

Manufacturers may also attempt to mitigate LOE by competing with generic or biosimilar entrants on price via contracting. Gross-to-net discounts for oncology drugs tend to widen as generic or biosimilar entry nears, as branded manufacturers lean into rebates to defend preferred access. Used strategically, these rebates raise the effective switching cost for payers and pharmacy benefit managers (PBMs) and blunt the economic case for generic or biosimilar competition.

The approach is most durable when the generic or biosimilar competitor's net-price edge is small or when payers cannot shift enough patients to the competitor to offset the rebate revenue they would lose on the originator's remaining book. Recent examples illustrate this range of tactics:

- AstraZeneca's Calquence growth (notably, pre-LOE) was partly driven by formulary discounts aimed at securing preferred payer placement.
- Novartis ensured exclusive use of Gleevec through payer and PBM contracts, paired with HCP outreach and patient programs designed to keep patients on the branded molecule.
- Takeda appeared to offer discounted contract prices to incentivize payers and institutions to continue using Velcade after generic bortezomib became available.

Rebate-based defense tends to break down when the generic or biosimilar net-price advantage is large, buyers are financially motivated to switch (e.g., Part B buy-and-bill margin, value-based-care shared savings) or multiple competitors enter in a short window. IV oncology biosimilars (e.g., for trastuzumab, bevacizumab and rituximab) have demonstrated this dynamic.

Implications:

Contracting is best deployed as a bridge to extend share during LOE and soften the transition, providing patients continuity of care. It is not a durable substitute for a genuine clinical, administration or total-cost-of-care advantage. Once the net-price gap exceeds what rebates can economically close, or once channel incentives (buy-and-bill economics, value-based-care contracts, pharmacist-led substitution) align against the originator, the rebate wall erodes quickly.

Initiate RWE studies to show the value of originator molecules beyond what generics or biosimilars can claim

While generic or biosimilar competitors can match or reference originator prescribing labels, the evidence base around real-world effectiveness, tolerability, adherence, quality of life and use in underrepresented subpopulations remains a durable point of differentiation.

Well-timed RWE programs, initiated several years ahead of LOE so that read-outs land during the transition window, can strengthen payer negotiations (by quantifying total-cost-of-care or outcomes benefits that a biosimilar dossier cannot replicate), reinforce clinician preference (by giving key opinion leaders and community oncologists a reason to specify the branded molecule beyond price) and improve patient retention through the LOE window (by supporting continuity-of-care arguments for patients already established on the originator). Herceptin and Avastin provide a couple of examples:

- **Herceptin:** HerSC real-world study in HER2+ early breast cancer patients across Europe, launched by Roche in 2013 (~one year before Herceptin EU LOE) to build a common evidence base bridging IV and sub-Q Herceptin before biosimilar trastuzumab entry, supporting the sub-Q franchise's differentiation narrative once biosimilar IV became available.
- **Avastin:** Multicountry MO30177 real-world effectiveness study in 1L mCRC (KRAS-stratified), started by Roche in 2016, around three years ahead of U.S. LOE and around four years ahead of the June 2020 EU LOE, to reinforce Avastin's place in chemotherapy combinations and generate use-pattern and outcomes evidence that biosimilar sponsors would not have.

Implications:

This strategy is not a panacea, but it can help identify where originator molecules are and aren't benefiting real-world patients and potentially soften erosion due to LOE. To make RWE a meaningful LOE-mitigation lever, manufacturers should:

- **Start early:** Initiate RWE studies at least three years before LOE so results are available for payer negotiations, guideline updates and HCP engagement during the transition window—not after biosimilar or generic entry has already reshaped share. The Darzalex program is instructive; Janssen began enrolling a prospective health-related quality of life and effectiveness cohort in 2020 while daratumumab was still deep in growth mode, yielding a mature evidence base available years ahead of biosimilar competition.
- **Target the evidence gaps biosimilars may miss:** Prioritize head-to-head or bridging comparisons across formulations (e.g., IV versus sub-Q), real-world subpopulations underrepresented in registrational trials, long-term safety and tolerability, adherence and persistence, patient-reported outcomes and total-cost-of-care outcomes.
- **Align RWE endpoints to stakeholder decision criteria:** Payer-facing studies should quantify total-cost-of-care and productivity outcomes; HCP-facing studies should focus on effectiveness in real-world patient mix and sequencing; patient-facing evidence should address quality of life and administration burden.
- **Pair RWE with contracting and reformulation strategies rather than substituting for them:** RWE is most powerful when it gives payers and clinicians a defensible reason to accept the branded contract or convert to a differentiated formulation, tying back to the reformulation and contracting levers described above.

In the U.S., oncology leaders are managing a market where the path from innovation to growth is becoming harder to control. Clinical differentiation still matters, but it is no longer enough on its own. Performance increasingly depends on whether companies can anticipate access constraints, support provider workflows and make disciplined investment choices across launches, inline brands and assets approaching loss of exclusivity.

In the U.S., the central challenge is turning strong science into sustained market impact in an environment where access, care delivery, policy and competition increasingly shape uptake, outcomes and value. You and your teams will need to start answering the following questions:

- Which of our top three current launches are we resourcing like “Game-changers” when the honest archetype is “Innovator” or “Opportunist”? And what resources could we reallocate by fixing that?
- How are we using AI to uncover and address structural barriers to inline brand growth?
- How are we ensuring that our IRA and LOE defense playbooks prioritize both benefit to patients and value to the brand?

Companies that can answer these three questions honestly and act on the answers will define oncology performance in the U.S. for the rest of the decade. Companies that cannot will keep watching their brands’ performance fail to meet forecast expectations.

Driving oncology growth in 2026

The next phase of oncology growth will not be won by pipeline volume alone or by applying the same launch playbook to every asset. It will belong to companies that connect global portfolio choices to market-level execution realities earlier and more deliberately. That means moving earlier in disease where opportunity is durable, aligning target and modality choices with differentiated science, treating evidence, access and launch sequencing as strategic inputs and preparing for IRA and LOE pressures before they compress the revenue window.

In the U.S., that discipline shows up in three places: launches that are resourced according to their true archetype, inline brands that keep growing by mitigating access and care-delivery friction and LOE strategies that protect value by creating a credible benefit for patients, providers or payers.

About the authors

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About ZS

ZS is a management consulting and technology firm that partners with companies to improve life and how we live it. We transform ideas into impact by bringing together data, science, technology and human ingenuity to deliver better outcomes for all. Founded in 1983, ZS has more than 15,000 employees in 40-plus offices worldwide.

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