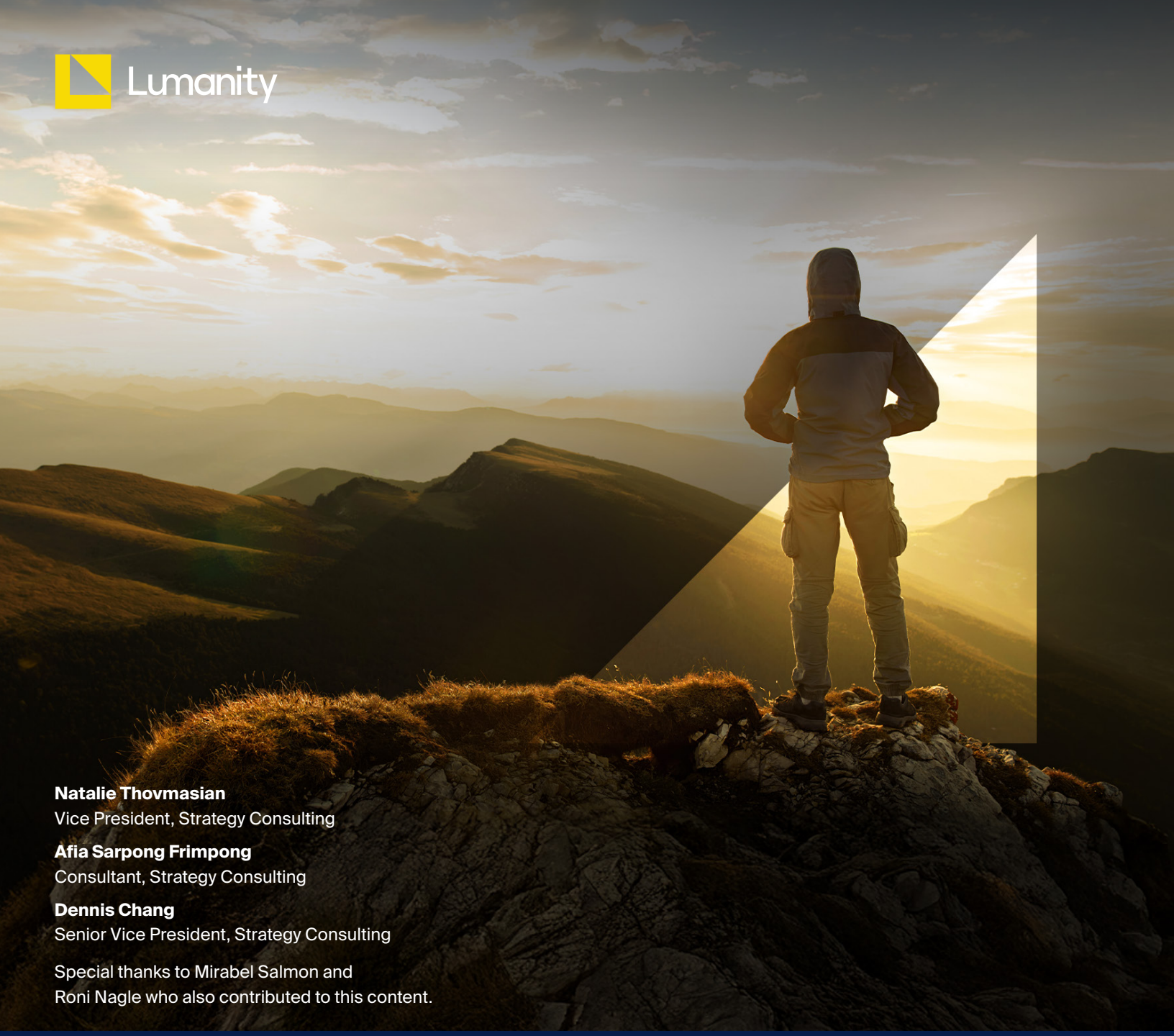


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Competition Drives Biopharma Innovation and Patient Impact

Next-in-class launches strengthen clinical differentiation and treatment choice in the U.S.

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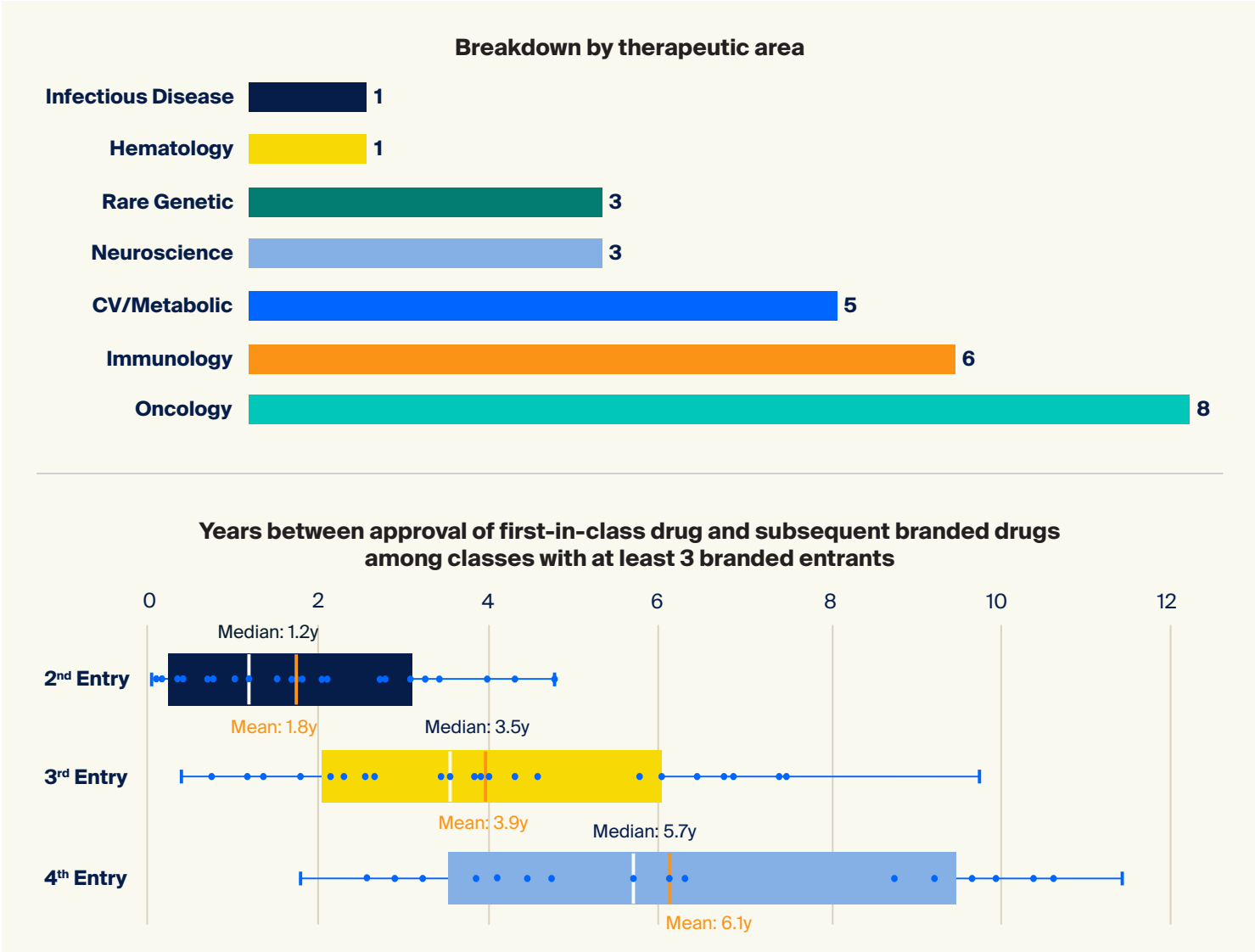
Executive Summary

Competition among branded medicines is a defining feature of the U.S. biopharmaceutical market, yet its scope and impact are often overlooked.

To better understand this dynamic, we examined the pace at which new branded competitors enter drug classes following a first-in-class launch and how those subsequent therapies create market-based competition and expand treatment options for patients.

This study identified that within the last two decades, more than 27 new drug classes—meaning groups of drugs that work in a biologically similar way—have included 3 or more brand-name competitors (Figure 1). These drug classes generate nearly a third of brand drug sales in the U.S. Among these high sales generating drug classes, the first branded competitor entered the market an average of 1.8 years after the first-in-class medicine. The second branded competitor entered on average 3.9 years after the first-in-class medicine. In all these drug classes, subsequent branded drug launches offered benefits such as differentiated efficacy, side-effect profiles, or dosing options.

Figure 1. Overview of drug classes established since 2005 with at least 3 branded entrants

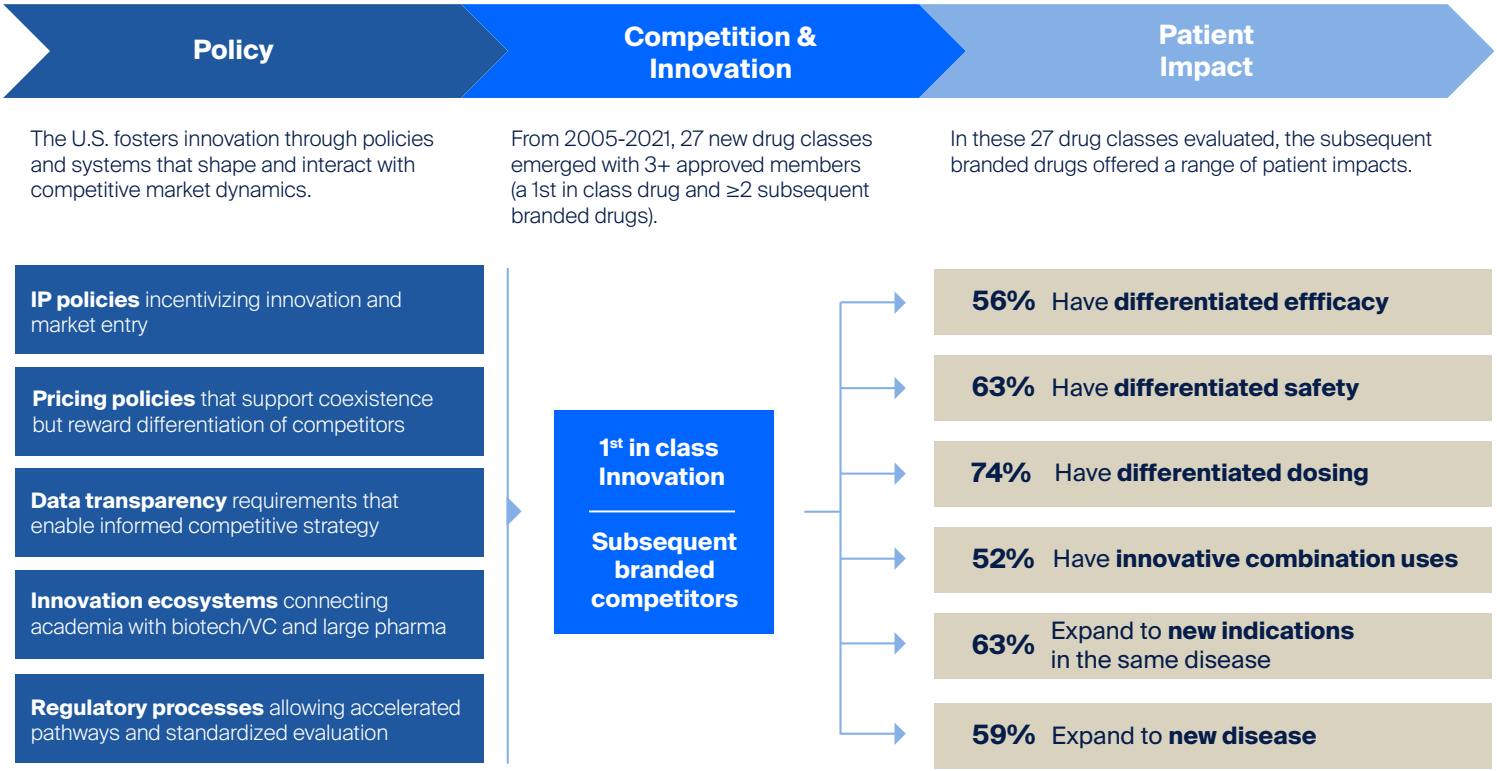


Executive Summary (cont)

Nearly 60% of subsequent branded competitors expanded treatment options for patients with diseases beyond those targeted by the original medicine, and nearly 3 in 4 introduced new dosing options to support convenience or adherence options for patients (Figure 2).

These findings underscore that competition in the U.S. market-based system successfully fuels not only first-in-class innovation but next-in-class innovation, encouraging competition while allowing clinical differentiation, therapeutic advancement, and patient choice to thrive.

Figure 2. Summary of Findings







Background & Policy Context

The breadth of medicines available to U.S. patients reflects an ecosystem that aligns incentives across the product lifecycle, from R&D through regulatory approval and market access.

Strong intellectual property protections, predictable and transparent science-based regulatory review, and a market-based coverage and reimbursement system enable differentiated therapies to compete for patient access. Together, these elements have supported a dynamic market characterized by continued innovation, therapeutic competition, and broad patient access to new medicines.

Intellectual property protections play a central role in balancing incentives for investment in new medicines while facilitating longer term generic and biosimilar competition. The development of new therapies is characterized by long timelines, significant capital requirements, and high rates of attrition. Patents and regulatory exclusivities provide a time-limited opportunity for successful therapies to generate returns that help offset the cost and risk associated with both successful and unsuccessful development programs.

The patent system also facilitates diffusion of scientific and technical knowledge as it requires patent disclosure to the public, while providing generic and biosimilar manufacturers with information necessary to bring low-cost versions of these products to the market once that exclusivity period expires.

The competitive effects of patent disclosure extend beyond facilitating eventual generic and biosimilar entry. Disclosure of a novel therapeutic approach through the patent system can signal both scientific potential and market opportunity for other innovative drug companies, encouraging R&D investment to invent around the disclosed invention and develop additional differentiated products within the same therapeutic class. In this way, an initial patented breakthrough can catalyze a broader cycle of follow-on innovation and competition, resulting in greater clinical differentiation and an expanded range of therapeutic options.

Over the last two decades, this dynamic has contributed to the emergence of numerous new therapeutic classes based on novel approaches to preventing and treating disease. For many of these classes, multiple companies have brought competing drugs to market, each seeking to differentiate their products on multiple dimensions in a way that addresses an unmet medical need and demonstrates distinct value to patients. This within-class differentiation is important as patients respond differently to drugs with the same mechanism of action, due to genetic variation, diet and lifestyle, comorbidities, tolerability, and drug interactions, among other factors.

Competition within a therapeutic class operates on two complementary dimensions: price and clinical differentiation. First, Pharmacy Benefit Managers (PBMs) and health plans play a central role in determining formulary placement and patient access as they design coverage policies for their enrolled populations, often leveraging multiple options within a class to negotiate substantial rebates and discounts, which can reduce the cost of medicines by 10, 20, and sometimes 50 percent or more. Second, and equally important, is competition based on clinical effects, which drives patient choice, therapeutic advancement, and medical progress. In this study, we characterize a set of drug classes to assess the intensity of competition, the types of innovation, and the depth and breadth of benefits that these innovations bring to patients.

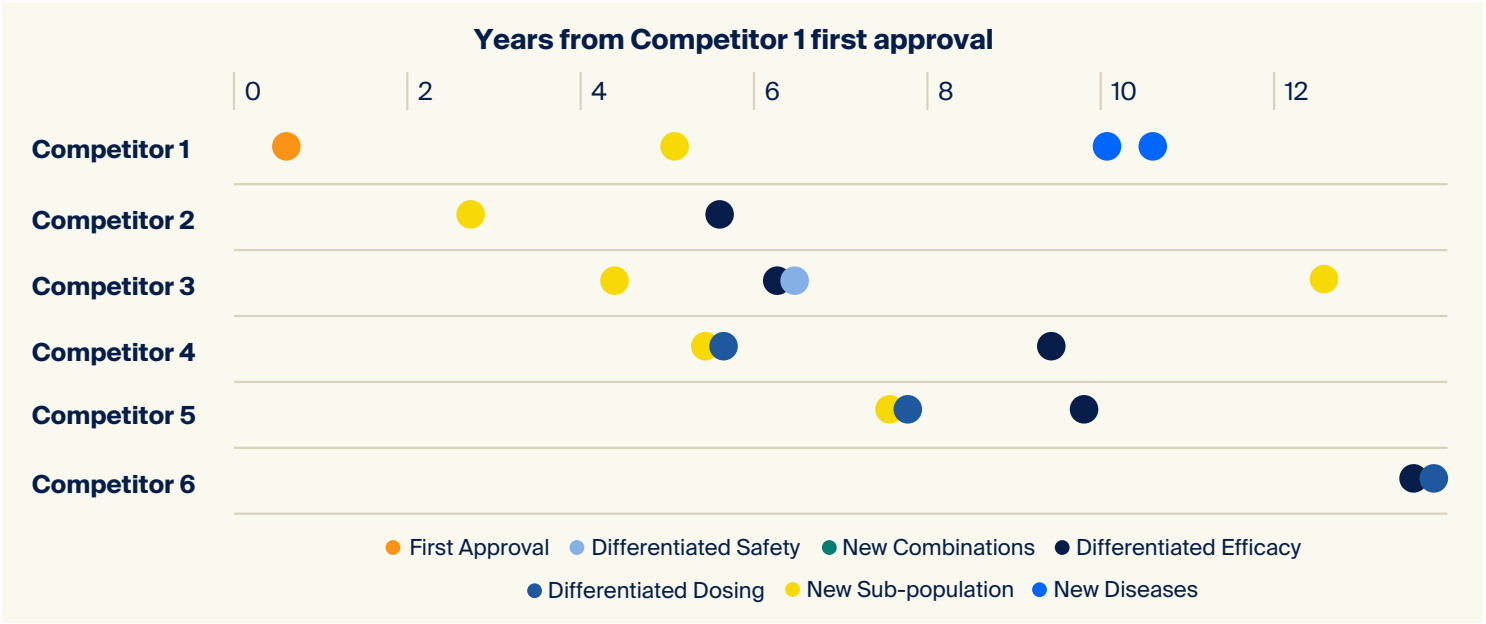
Key Findings and Case Studies

Our analysis finds that continued innovation within drug classes by additional branded therapies is widespread.

Every drug class established since 2005 that had 3 or more total competitors produced continued patient-centric innovation in one or more of the dimensions assessed: efficacy, safety, dosing/convenience, combination use, specific sub-indications (i.e., expanding use to new patient subpopulations within the same disease type), and new indications (i.e., expanding use to new diseases). This was true of branded competitors across all therapeutic areas and drug modalities, from traditional pills to antibody-based therapies and cutting-edge cell and gene therapies.

Here we describe 6 examples as case studies involving an innovative first-in-class (FIC) drug approval, as well as subsequent branded competitors, which led to differentiated options and expanded value for patients.

Case Study 1: Targeting Cancer Mutations with ALK Inhibitors

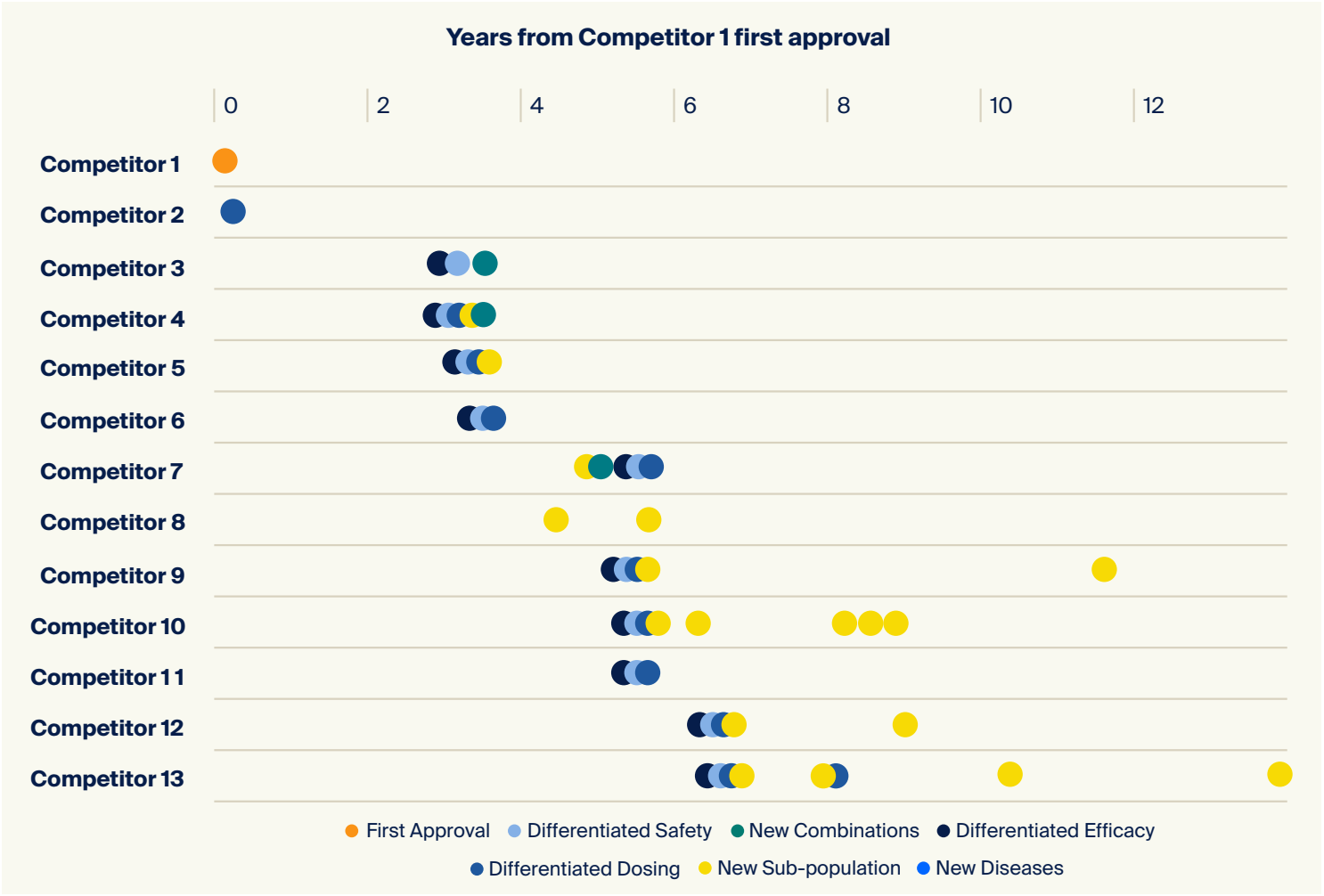


Note: Case study is non-exhaustive

Innovation through expansion of targeted efficacy

- Anaplastic lymphoma kinase (ALK) is a gene that, when mutated or abnormally fused with another gene, produces a protein that drives uncontrolled cell growth and division; this genetic alteration is found in a subset of non-small cell lung cancer patients and can also occur in other cancer types, making tumors reliant on ALK signaling to survive and spread.
- The FIC drug in this class introduced a new treatment option for lung cancer patients with specific ALK alterations found in their tumors. Importantly, this treatment option was chemotherapy-free. The FIC drug continued to expand its benefits over time to additional patient populations, including other cancer types with ALK alterations.
- In cancer, it is common for additional mutations to develop, leading to cancer growth and treatment resistance. To tackle this issue, five subsequent branded competitors were designed to have efficacy in situations where the ALK gene develops additional mutations. These drugs offered a differentiated efficacy profile compared to the FIC drug.
- Continued competition and innovation within the class led to further advances in efficacy, including therapies that can provide patients with years of cancer control.
- Another drug showed a differentiated safety profile compared to the FIC drug, supporting its use in earlier-stage cancer, right after surgery.

Case Study 2: Direct-Acting Antivirals to Cure Hepatitis C

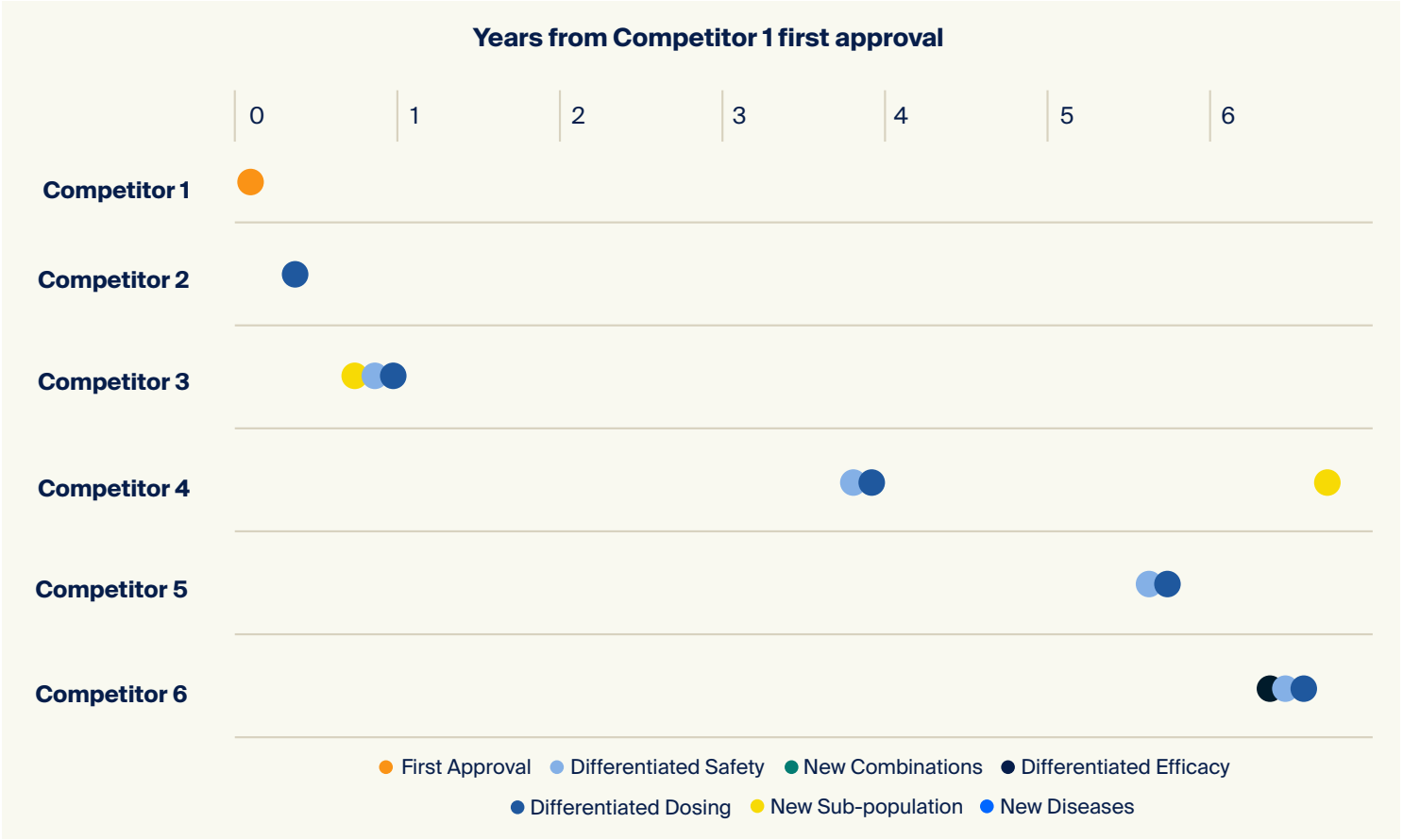


Note: Case study is non-exhaustive

Innovation enabling more cures

- Hepatitis C is a viral infection that attacks the liver; left untreated, chronic infection can progressively scar the liver (cirrhosis) and lead to liver failure or liver cancer over time.
- Direct-acting antivirals (DAAs) target specific proteins the Hepatitis C virus needs to multiply, directly interrupting its replication process rather than relying on the immune system to clear the virus.
- The first approved medicine in this class was a pill added on top of existing treatment regimens, (some of which were delivered via subcutaneous injection), and meaningfully improved cure rates for the most common form of Hepatitis C.
- However, the combination regimen for the FIC drug came with difficult flu-like side effects that made it challenging for many patients to tolerate.
- The 4th branded competitor was the first treatment for Hepatitis C associated with cure rates in excess of 90 percent that could achieved without a combination regimen, delivering an improved tolerability profile while simultaneously offering significant improvements in cure rates since the first DAAs launched.
- As subsequent branded competitors no longer required combination use, these later competitors provided the first oral pill regimens, along with shorter treatment courses (as short as 8 weeks, rather than up to 48 weeks).
- Later branded competitors brought access to subgroups of patients who lacked an available DAA, including those with different strains of Hepatitis C (made possible by pan-genotypic DAAs), patients also living with HIV, those with advanced liver disease, and people with kidney problems.

Case Study 3: TTR-Targeted Treatments for a Rare Disease

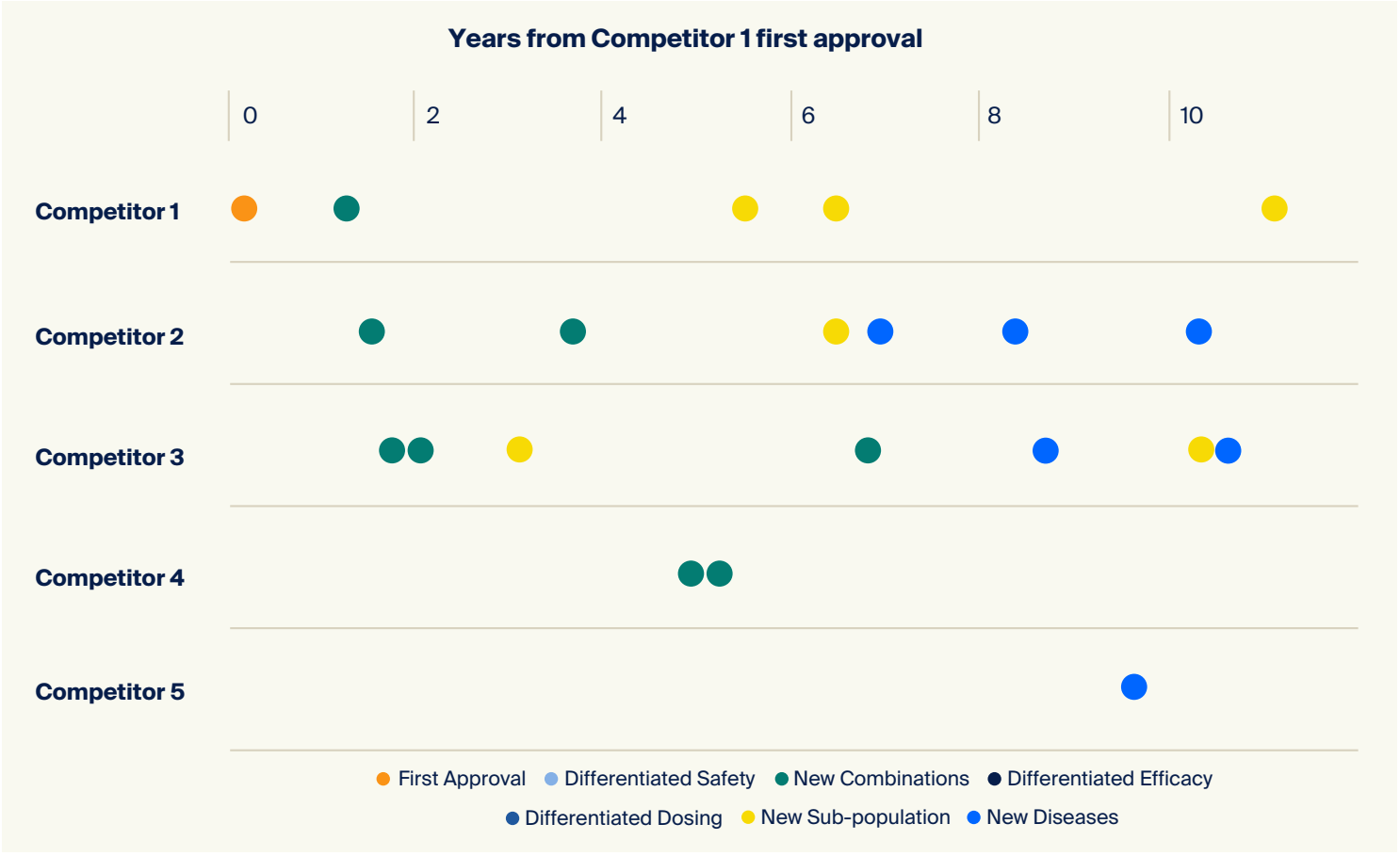


Note: Case study is non-exhaustive

Innovation through safety profiles

- Transthyretin amyloidosis (ATTR) is a rare and serious disease in which a protein called transthyretin (TTR) that is normally responsible for transporting hormones and vitamins through the bloodstream. In ATTR, the TTR protein misfolds, clumps together, and builds up, progressively damaging organs.
- ATTR can damage peripheral nerves (called polyneuropathy) or accumulate in the heart muscle, forming ATTR cardiomyopathy (ATTR-CM). Both result from the same underlying disease process. Disease-modifying therapies have been developed to target the TTR pathway through two main approaches: TTR silencers reduce production of the protein, while TTR stabilizers help prevent it from misfolding.
- The first approved medicine from this class treated the nerve form of this disease and worked by dramatically reducing—by roughly 80%—the amount of TTR circulating in the body. Treatment involved patients receiving an intravenous infusion every 3 weeks and taking additional medications beforehand to manage side effects.
- Subsequent innovation expanded treatment options to ATTR-CM, a serious manifestation associated with heart failure and death. Three branded medicines received approval to treat this form of the disease.
- For the nerve disease form of ATTR, the 4th and 5th branded competitors provided effective options to reduce the protein but without requiring patients to undergo regular blood tests to monitor for potential damage to platelets or the kidneys. This simplification reduced the burden on patients.
- For the heart disease form of ATTR, one branded competitor uses a different disease targeting strategy, stabilizing the problem protein before it misfolds. This drug is administered in pill form, further differentiating it from infusion-based treatments.

Case Study 4: How Competition Among Diabetes Drugs Unlocked Breakthroughs in Heart and Kidney Disease

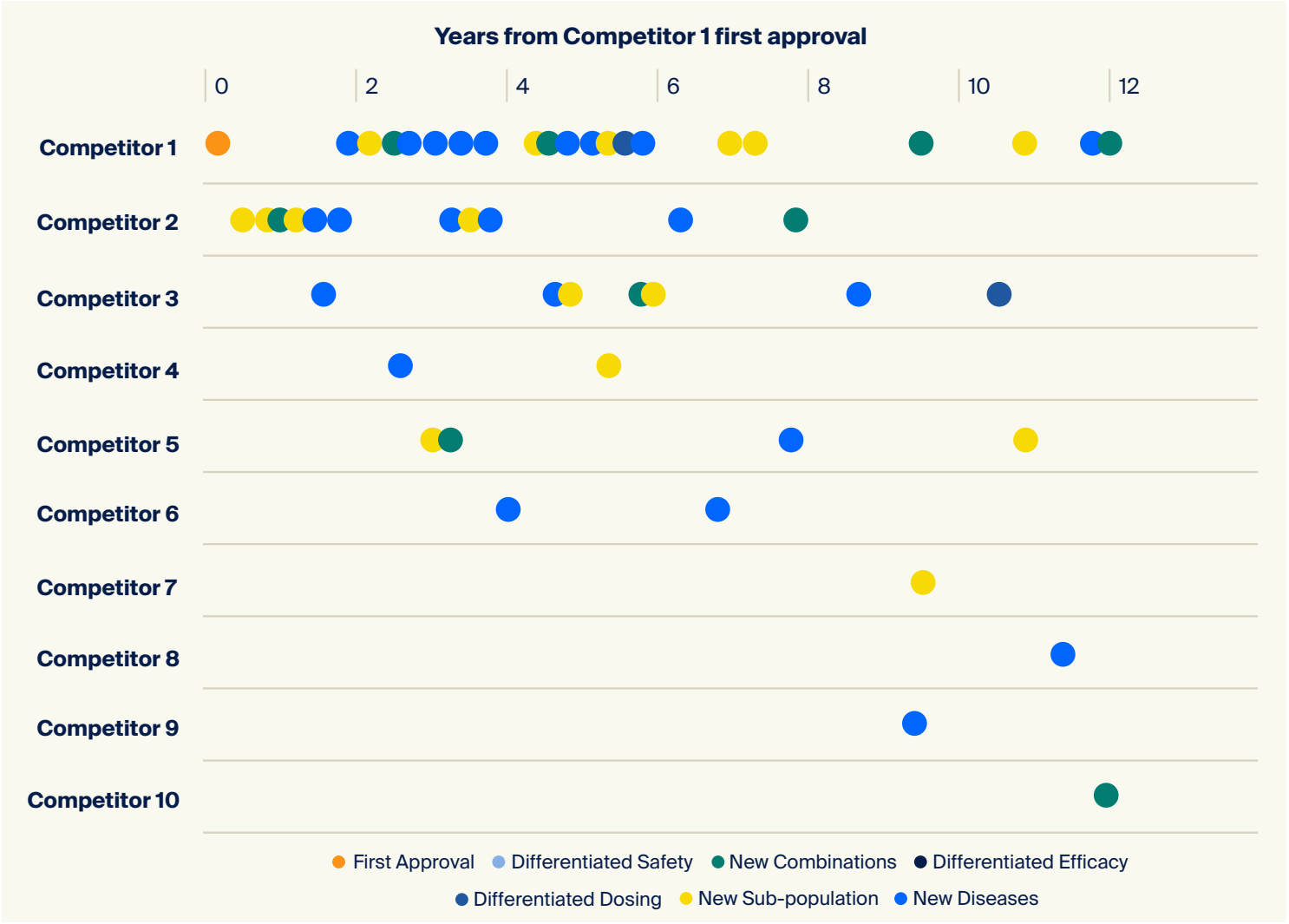


Note: Case study is non-exhaustive

Innovation through expansion to new patient groups

- Type 2 diabetes is a chronic condition in which the body becomes resistant to insulin or doesn't produce enough of it, leading to elevated blood sugar levels that, over time, can damage blood vessels and organs, contributing to heart disease, kidney disease, and other complications.
- SGLT2 inhibitors work by blocking a protein in the kidneys responsible for reabsorbing glucose back into the bloodstream, causing excess sugar to be excreted in urine instead.
- The first drug in the SGLT2 inhibitor class was approved to help lower blood sugar in patients with Type 2 diabetes.
- What wasn't known at the time was how much further its benefits would reach. Through years of large-scale clinical trials involving tens of thousands of patients, researchers observed that members of this drug class could also significantly reduce the risk of heart failure hospitalization, slow the progression of kidney disease, and even lower the risk of death from cardiovascular causes.
- Three of five subsequent branded competitors differentiated by gaining approvals for reduction of heart failure, treating chronic kidney disease, and lowering rates of cardiovascular death.
- Several of the drug developers also developed new drug products, combining the SGLT2 inhibitor with one or two other diabetes drug types into single pills, resulting in differentiated efficacy and expanded treatment options for patients to flexibly manage their diabetes and other co-occurring conditions.

Case Study 5: Anti-PD-(L)1 Immunotherapy in Cancer



Note: Case study is non-exhaustive

Innovation through new patient populations, combinations, and dosing

- In many cancer types, cancer cells can exploit the PD-(L)1 pathway—a natural checkpoint that prevents the immune system from attacking healthy cells—to evade immune detection and continue growing.
- The first medicine in the anti-PD(L)1 immunotherapy class led to durable responses in several cancers that were unresponsive to conventional chemotherapy.
- While the initial entrant continued to build evidence and innovate to benefit patients across dozens of cancer types, 75% of subsequent brand competitors that launched treated distinct patient populations from the FIC medicine, including new cancer types or new subgroups of patients.
- Multiple branded competitors have developed alternative dosing options. For example, subcutaneous injections are administered under the skin and can be completed in minutes. IV infusions are administered through a needle inserted into a vein and can take half an hour or longer.
- Five drugs in this class became available for use in combination with other drugs, offering the benefits of this type of immunotherapy to groups of patients in which a single drug was not sufficient.

Conclusion

The findings presented here carry a clear message: within the therapeutic classes examined, competition among branded medicines is not a race to copy; it is a race to improve, with patients, society, and medical progress as the ultimate beneficiaries. Critics sometimes dismiss later entrants as mere “me-too” drugs, but the case studies in this brief tell a different story. Each new entrant typically offers something meaningfully different in terms of patient outcomes, safety profile, dosing schedule, or access for a new patient population not previously served. The presence of multiple competitors within a therapeutic class creates ongoing incentives for companies to differentiate their products and invest in innovations that address remaining unmet need.

The IP system plays an important role in shaping competition across the lifecycle. Time-limited IP protections create incentives for FIC innovation, while patent disclosure and opportunities for differentiation can encourage additional investment and competition within therapeutic classes. When that period ends, the framework transitions to generic and biosimilar competition, enabling prices to fall substantially and durably, benefiting patients and the system over the long run. The result is a three-stage lifecycle: novel FIC innovation; innovation within the class more broadly; and long-term affordability of a wide range of therapeutic options.

Sustaining this competitive lifecycle requires a policy environment that supports investment not only in FIC breakthroughs, but also in continued innovation within established classes. Government price-setting of a medicine before generic or biosimilar competition would otherwise occur can affect the investment economics of other therapies in development within the same class by introducing competition with artificially reduced prices into this lifecycle. Over time, this could reduce investment in follow-on medicines and the competition that drives therapeutic advances in efficacy, safety, convenience, and patient reach.

Taken together, the findings presented in this brief illustrates how the U.S. intellectual property, regulatory, and market-access framework supports competition across the lifecycle. Preserving this balance is essential to sustaining a dynamic biopharmaceutical market and to ensure the US continues to lead the world in developing new therapeutic advances over time.

Additional Reading

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Appendix Methodology

We defined a 'drug class' as a group of medicines that work by targeting the same biological mechanism in the body: essentially, different companies' attempts to treat the same disease **by affecting the same molecular target or pathway**.

We further refined the set of drug classes to analyze using the following criteria:

- **Recent development:** The drug class was founded in 2005 or later, i.e. the first-in-class (FIC) drug received its first FDA approval no earlier than 2005.
- **Robust competition:** The drug class has at least 3 entrants as of 2026: the FIC drug and at least 2 subsequent branded competitors. Moreover, we focused our analysis on drug classes where the second-in-class drug received approval no more than 5 years after the FIC drug.
- **Robust impact:** The drug class has had at least $1 billion in net sales in at least one calendar year, indicating substantial utilization.
- **Active treatment:** We focused on drugs used to treat a diagnosed disease, excluding preventative drugs such as vaccines.

We then characterized each drug within each class in terms of any innovation it offered across the following dimensions:

- **Differentiated efficacy:** Examples of evidence include statistically significant improvement in a head-to-head clinical trial or strong efficacy data in a cross-trial comparison of similar clinical studies, and validated by published expert perspectives.
- **Differentiated safety or tolerability:** A subsequent branded competitor shows a different profile of adverse events (e.g., fewer or less severe adverse events of a certain kind)
- **Dosing schedule or convenience:** New options for how a branded drug is administered, supporting greater convenience and choice for patients. Examples include reformulating a drug so that it can be taken at home, reducing the infusion time, reducing the infusion frequency, or reducing the pill burden.
- **Combination innovation:** New evidence supports approval of using a drug in the class in combination with one or more other drugs, creating a novel combination regimen.
- **Sub-indication expansion:** New evidence supports approval of a drug for a different patient population in the same disease state as a prior approval for the drug class. Examples might include use of a drug in an earlier treatment setting or a distinct disease subtype as the FIC drug.
- **New indication expansion:** New evidence supports approval of a drug in the class for a different disease than prior approvals in the class.

To characterize each drug class, we reviewed FDA-approved prescribing labels, results from clinical trials, clinical treatment guidelines, and published commentary from leading medical experts.

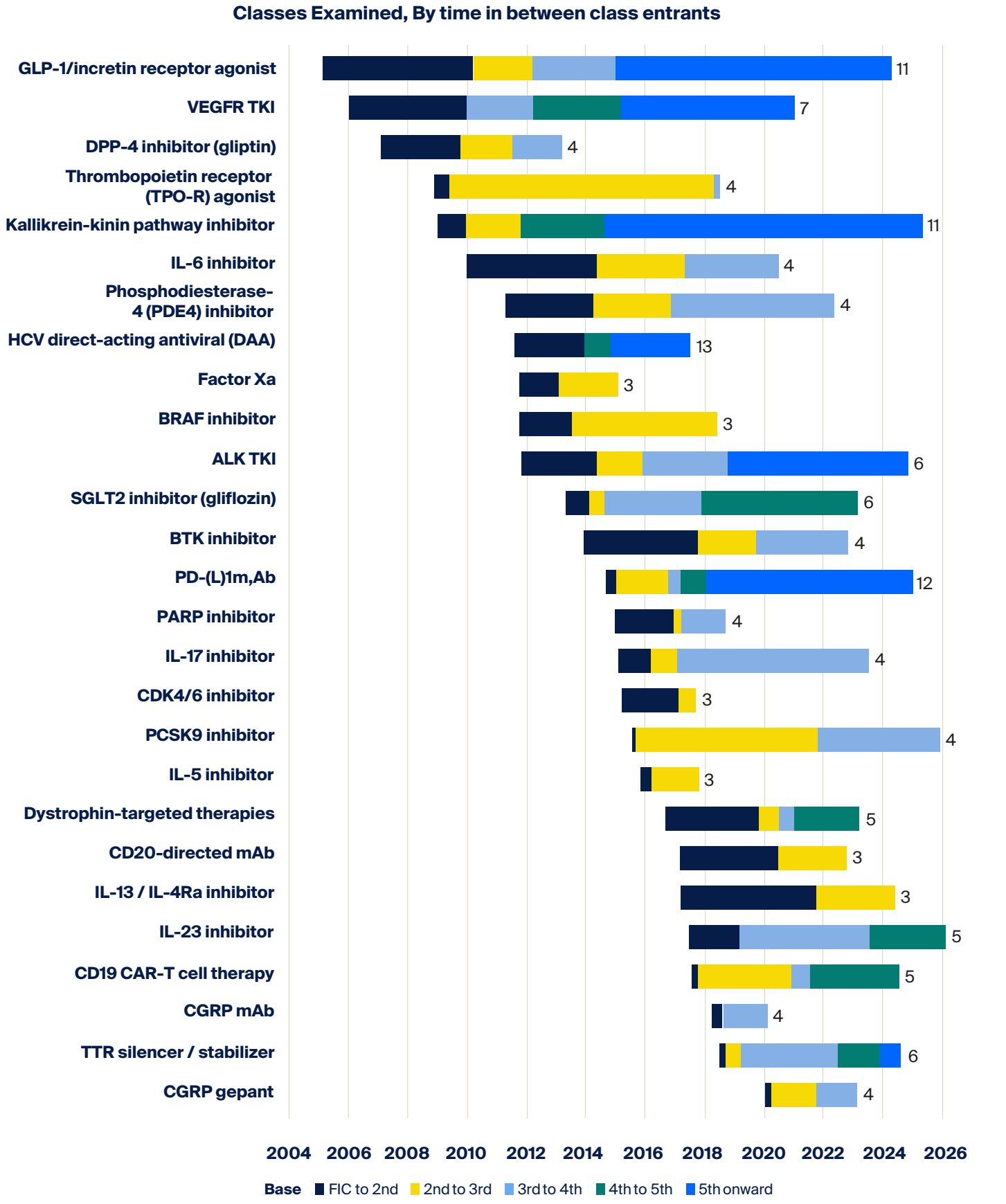
Secondary research sources for case studies: FDA approval labels and Drugs@FDA approval histories for each agent (indications, dosing schedules, combination requirements, and safety statements), company annual reports and press releases. Note the case study figures focus on key innovations and do not exhaustively show the approval history of every drug.

Supplemental Figure 1. Summary of 27 Drug Classes Identified in this Analysis

Included were all therapeutic drug classes with 3+ entrants, FIC FDA approval between 2005 and 2021, 2nd entrant in less than 5 years after the FIC, and where at least one entrant achieved $1B in peak sales. Vaccines were excluded.

TA	Drug class	Time from 1st to 2nd entrant	Total # entrants as of H1 2026
Infectious Dis.	HCV direct-acting antiviral (DAA)	10 days	13
CV / Metab	PCSK9 inhibitor	1 month	4
Oncology	CD19 CAR-T cell therapy	1 month	5
Oncology	VEGFR TKI	1 month	7
Rare genetic	TTR silencer / stabilizer	1 month	6
Neuroscience	CGRP gepant	2 months	4
Hematology	TPO-R agonist	3 months	4
Neuroscience	CGRP mAb	3 months	4
Immunology	IL-5 inhibitor	4 months	3
Oncology	PD-(L)1 mAb	4 months	12
Immunology	IL-23 inhibitor	8 months	5
CV / Metab	SGLT2 inhibitor (gliflozin)	9 months	6
Rare genetic	Kallikrein-kinin pathway inhibitor	11 months	11
Immunology	IL-17 inhibitor	1 yr, 2 mo	4
CV / Metab	Factor Xa inhibitor	1 yr, 6 mo	3
Oncology	BRAF inhibitor	1 yrs, 9 mo	3
Oncology	PARP inhibitor	2 yrs, 0 mo	4
Oncology	CDK4/6 inhibitor	2 yrs, 1 mo	3
Immunology	PDE4 inhibitor	2 yrs, 8 mo	4
Oncology	ALK TKI	2 yrs, 8 mo	6
CV / Metab	DPP-4 inhibitor (gliptin)	2 yrs, 9 mo	4
Rare genetic	Dystrophin-targeted therapy	3 yrs, 2 mo	5
Neuroscience	CD20-directed mAb	3 yrs, 4 mo	3
Oncology	BTK inhibitor	3 yrs, 11 mo	4
Immunology	IL-6 inhibitor	4 yrs, 3 mo	4
CV / Metab	GLP-1 agonist	4 yrs, 9 mo	11
Immunology	IL-13 inhibitor	4 yrs, 9 mo	3

Supplemental Figure 2. Drug Classes Examined, by Timing between First-in-Class Approval and Subsequent Branded Approvals



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