



EXECUTIVE INSIGHTS

When Is It Too Late? Drivers of Commercial Performance for Late Entrants in Biopharma

Key takeaways

- Second or later entrants in the U.S. market are more likely to achieve commercial success if launched within two years of the first-in-class product.
- Entrants launching beyond the two-year window can still be successful but almost always demonstrate clinically meaningful advantages in efficacy and/or safety to compete effectively.
- Large pharmaceutical companies are better positioned to succeed with late entrants, leveraging their scale, experience and resources to compete commercially and manage the product life cycle.
- For executives pursuing a late-market entry, success depends on accelerating time to market and clearly differentiating the product. Without meaningful advantages and sufficient resources, the window of opportunity can close quickly.

Introduction

While first-to-market biopharma products in a new therapeutic class are often seen as having a clear competitive advantage, recent trends tell a more nuanced story. Over the past decade, around half of all innovative branded biopharma launches

have been second or later entrants within their therapeutic class (late entrants). Some have successfully reshaped the standard of care — offering superior efficacy, safety and/or convenience — and have achieved strong commercial performance. Others, however, have struggled to gain traction,

falling short of expectations with disappointing sales and minimal market impact.

As competition within therapeutic classes intensifies, critical questions emerge: When does it make strategic sense to develop a late entrant – and when is it simply too late? More importantly, what factors determine success for those entering an already-crowded field?

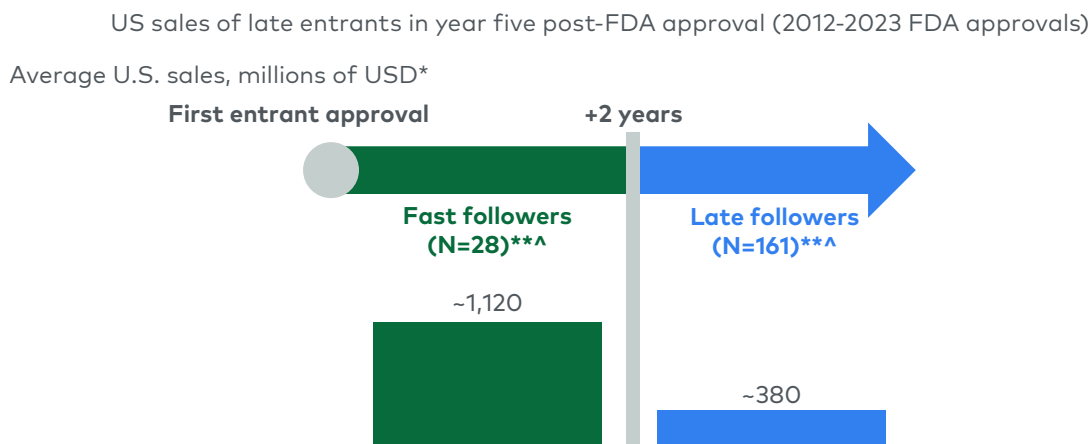
Followers fare better within two years of first launch

In the first two years following the launch of a new therapeutic class, the treatment landscape remains fluid, with physician adoption still evolving. This period offers fast followers – those entering the market within two years after the first-in-class entrant – a strategic window to capitalize on market

dynamics and shape prescribing habits. With a stronger clinical profile, fast followers can capture substantial market share and, in some cases, even outperform the first-in-class entrant.

As time passes, physician and patient familiarity and comfort with early entrants tend to deepen, leading to entrenched prescribing habits and growing loyalty to established brands. This creates a high barrier to entry for later competitors, which must offer a clearly differentiated value proposition to displace existing treatments. As a result, fast followers outperform late followers significantly, achieving nearly three times the average sales (see Figure 1). This performance gap underscores the importance of timing, strategic positioning and rapid execution in competitive therapeutic classes.

Figure 1



*Includes forecast data where applicable

**Not exhaustive, as some 2012-2023 entrants did not have sales data available

^Includes new molecular entity and original biological product approvals from the Center for Drug Evaluation and Research and innovative products approved by the Center for Biologics Evaluation and Research; excludes vaccines, products launched by same company as the first entrant, products that were add-on therapies to first entrant even though they were in the same therapeutic class, products under litigation and select other special situations that confound order-of-entry analysis

Note: FDA=Food and Drug Administration

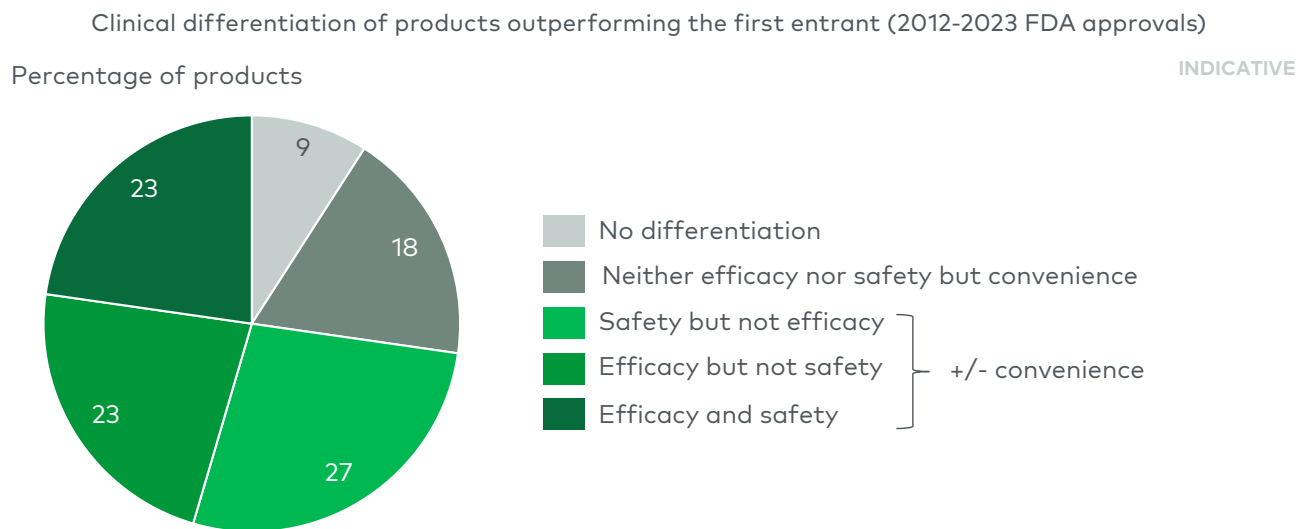
Source: Evaluate Pharma; FDA; company websites; press releases; L.E.K. research and analysis

Differentiation can drive success for late entrants

Despite the well-known challenges of entering the market behind a first-in-class agent, there are notable success stories. Among the 189 late entrants analyzed, 18 achieved over \$1 billion in U.S. sales within five years of launch and 22 outperformed order-of-entry-based sales expectations relative to the first-in-class product.^{1,2}

Most of the high-performing followers shared a common trait: a clearly superior efficacy and/or safety profile compared to the first entrant, highlighting the critical role of meaningful clinical differentiation in overcoming the disadvantages of later entry (see Figure 2).

Figure 2



Note: FDA=Food and Drug Administration
 Source: Evaluate Pharma; FDA; company websites; product labels; published studies; press releases; L.E.K. research and analysis

Nearly half of the followers that outperformed did so primarily through superior efficacy, often demonstrated in head-to-head trials against the earlier entrants. For example, the anaplastic lymphoma kinase (ALK) inhibitor Alecensa reduced the risk of progression or death by nearly 50% compared to Xalkori in ALK-positive non-small cell lung cancer, while the integrase strand transfer inhibitor Tivicay

showed a higher barrier to resistance than Isentress in the treatment of HIV.

About a quarter of outperformers differentiated on safety rather than efficacy. In these cases, the improvements were often significant — such as eliminating a black box warning present on the first entrant (e.g., Farxiga, which lacked the amputation risk warning seen with earlier sodium-glucose transport protein 2 inhibitors) or markedly

reducing serious adverse events such as hematologic or cardiovascular complications.

While follower outperformance based solely on convenience is less common, it is possible — particularly in chronic, non-life-threatening conditions such as asthma, migraine or psoriasis. In these cases, enhancements such as longer dosing intervals or transitioning from injectable to oral formulations played a role, often alongside other success factors such as rapid indication expansion.

Large biopharma companies have an advantage

Large biopharma companies (with market capitalizations over \$40 billion) hold a distinct advantage when launching a later entrant. Their robust commercial infrastructure, deep

industry experience, extensive customer networks and strong life cycle management capabilities enable them to drive significant market impact — even without a first-mover advantage. These companies can invest in differentiated clinical trials and large-scale marketing efforts, helping them stand out in competitive spaces. As a result, they account for a disproportionate share of products that ultimately outperform first-to-market competitors (see Figure 3).

In contrast, smaller companies face significantly greater challenges. Of the more than 40 late entrants they commercialized, none outperformed the first entrant.

Figure 3

Distribution of late-entrant launches by commercializing company size in year three (market cap) (2012-2023 FDA approvals)

Percentage of products*

	All products (N=189)	Outperformers^ (N=22)
Large** (>\$40 billion)	55% (104)	82% (18)
Mid** (\$5 billion to \$40 billion)	21% (39)	18% (4)
Small** (<\$5 billion)	22% (42)	0% (0)
Private	2% (4)	0% (0)

*Products without U.S. sales data, vaccines and other special circumstances as previously described have been excluded

**Company size defined by market capitalization in year three of product commercialization; in case of co-promotions, the size of the larger company was used; products launched by one company but acquired by another company by year three would be categorized based on the market cap of the acquirer; for products not yet three years into commercialization, the most recent market capitalization (winter 2025) was used

^With at least \$300 million in U.S. sales in year five post-FDA approval

Note: FDA=Food and Drug Administration

Source: FDA; Evaluate Pharma; company websites; press releases; L.E.K. research and analysis

When is it too late to launch a late entrant?

The answer is nuanced, but timing, differentiation and company scale are the critical drivers of success.

For products with strong differentiation — particularly in efficacy and/or safety — it may never be too late to enter. A compelling clinical value proposition can persuade physicians to switch, even for latecomers. However, the bar is high: Differentiation must translate into meaningful patient benefits and outcomes, not just statistically significant improvements on clinical end points.

For products that are more than two years behind the first-in-class product and lack clear differentiation, executives should carefully reassess further investment. If return-on-investment (ROI) projections are weak, it may be prudent to redirect development efforts toward targeted patient subgroups or alternative indications where there is unmet need or competitive intensity is lower. This consideration is especially important for smaller companies, which rarely succeed with undifferentiated late entrants. In more challenging scenarios, partnering or out-licensing may offer a strategic path to unlock value while reallocating resources toward assets with higher potential in the portfolio.

To increase the likelihood of success, executives managing late entrants should consider the following six strategic actions:

- 1. Assess differentiation and ROI early:** Rigorously evaluate the product's potential for clinical differentiation and expected ROI — especially if launch is more than two years behind a first-in-class competitor.
- 2. Scale investment strategically:** Right-size investment levels to reflect the increased difficulty of gaining market share.
- 3. Prioritize efficacy differentiation:** Focus development efforts on demonstrating superior efficacy, which remains the most compelling driver of prescriber adoption.
- 4. Highlight safety advantages:** Evaluate whether the product offers a more favorable safety profile — particularly in therapeutic areas where safety concerns heavily influence prescribing behavior.
- 5. Don't overweight convenience:** Avoid relying solely on convenience-based features (e.g., dosing, administration route) to drive differentiation; while occasionally successful, this strategy rarely leads to market outperformance on its own.
- 6. Consider strategic partnerships:** Smaller biotech firms should explore partnerships or licensing opportunities with larger, more experienced companies to improve launch execution and long-term success potential.

A well-timed and clearly differentiated product can still perform strongly as a late entrant. But without meaningful advantages and adequate resources, the opportunity for success may quickly close.

The authors would like to thank Katherine Taylor and Katharina Novikov for their important contributions.

For more information, please [contact us](#).

Endnotes

¹See methodology box for definition of outperformance. Some of the products were not assessed for outperformance due to missing first-entrant sales data from Evaluate Pharma.

²With 30 unique products across these two groups.

Methodology

Definition of therapeutic class: A mechanism of action within a disease or group of diseases.

Definition of outperformance: Generating more U.S. sales in year five post-Food and Drug Administration approval, relative to the first entrant, than would be expected by industry-standard order-of-entry share expectations. In all analyses, products were only considered outperformers if they also generated at least \$300 million in year-five U.S. sales.

Definition of differentiation: A clinically meaningful improvement from the first entrant in the class based on (1) head-to-head trials directly comparing efficacy or safety, (2) indirect comparisons of clinical data, or (3) broader attributes not requiring published comparisons, such as label enhancements (e.g., removal of black box warnings) or convenience benefits.

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