DOLON

From launch to legacy:
Pricing excellence through forecasting & analytics

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All opinions our own

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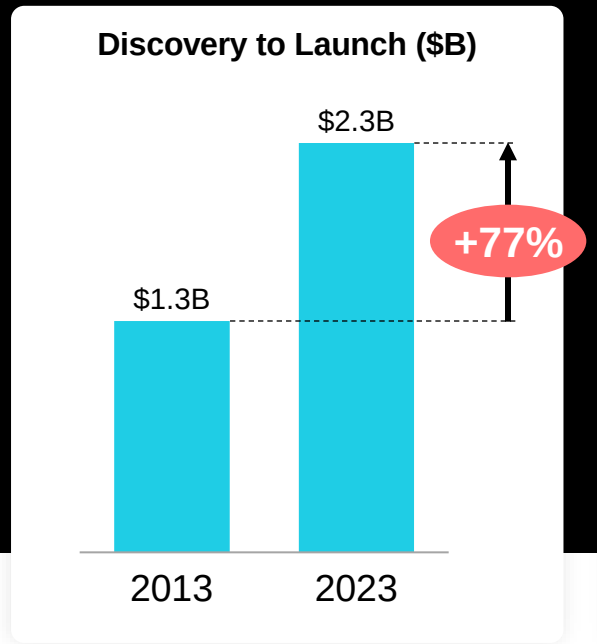
The business of developing and launching medicines has become increasingly difficult

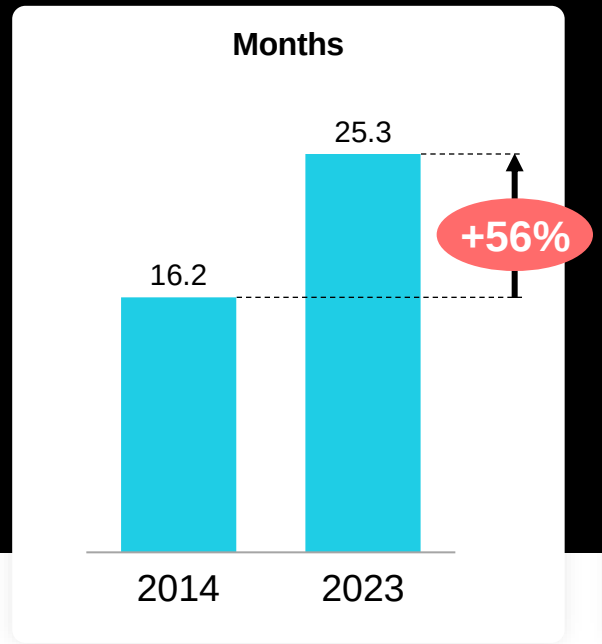
COST

Average R&D cost to develop a therapy[1]



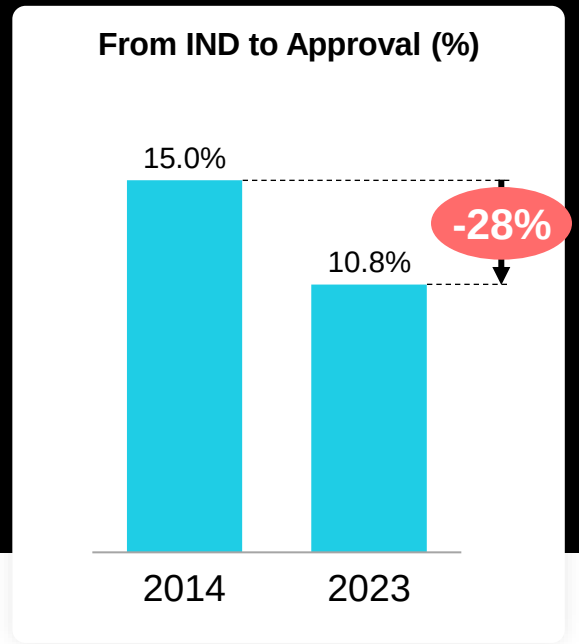
TIME

Enrolment duration for industry-sponsored trials[2]



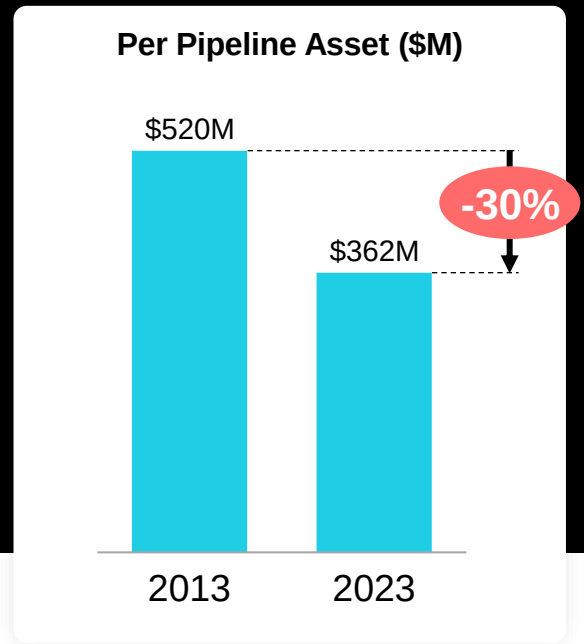
RISK

Composite success rates[3]



RETURN

Average peak sales[4]



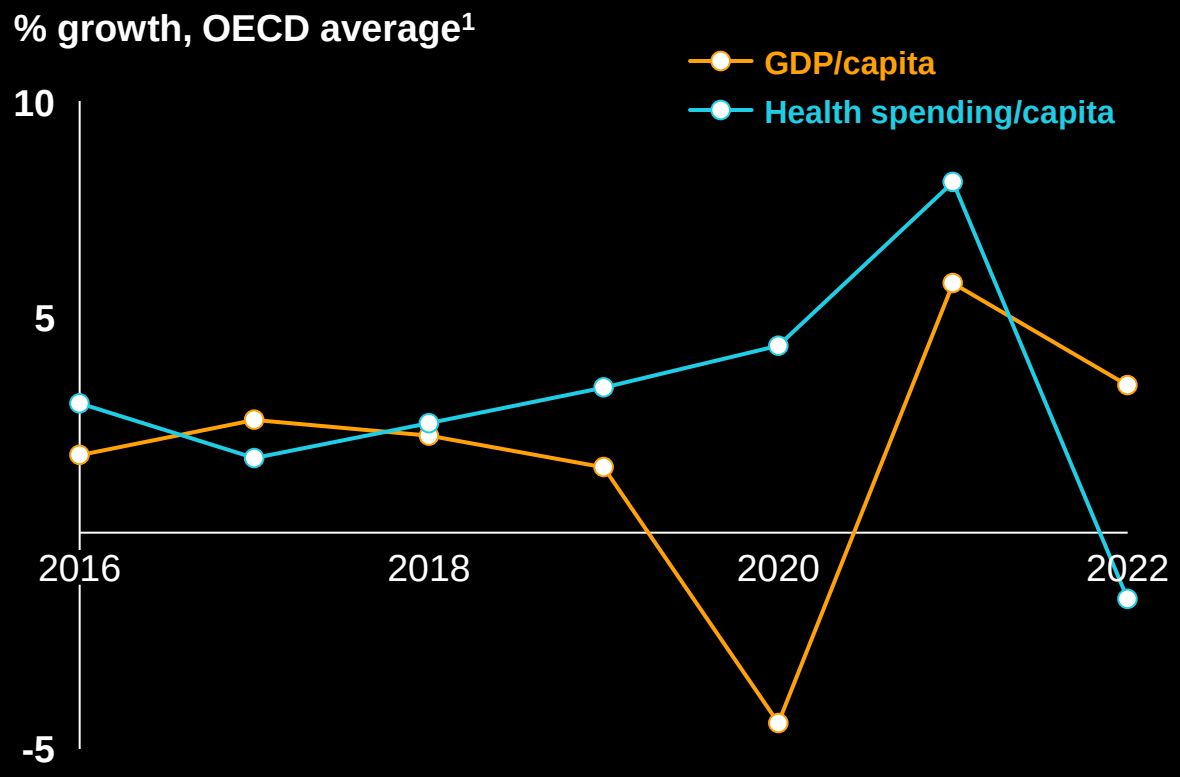
Adapted from Atlas Venture 2024 Year in Review

Now, more than ever, it is important to protect returns (i.e., price) for commercialized medicines

References: 1. Deloitte Annual Report on the Returns from Pharmaceutical Innovation (April 2024); 2. IQVIA report "Rethinking Clinical Trial Country Prioritization" (2024); 3. IQVIA "Global Trends in R&D 2024"; 4. Deloitte Analysis (April 2024)
Abbreviations: IND: Investigational new drug; R&D: Research and development

We are in an era of squeezed healthcare budgets and increased management of drug pricing

Amidst a backdrop of increasing financial pressure on healthcare systems…



…new policies are being introduced to manage pharmaceutical spend and pricing

Inflation reduction act

Medicare price negotiations for select Part B/D drugs[2]

SHI financial stabilization

Updated pricing guardrails and Orphan drug privilege threshold reduced to €30m[3]

CEPS price reductions

Pricing committee set a target of €1 billion in savings via drug price cuts for 2025[4]

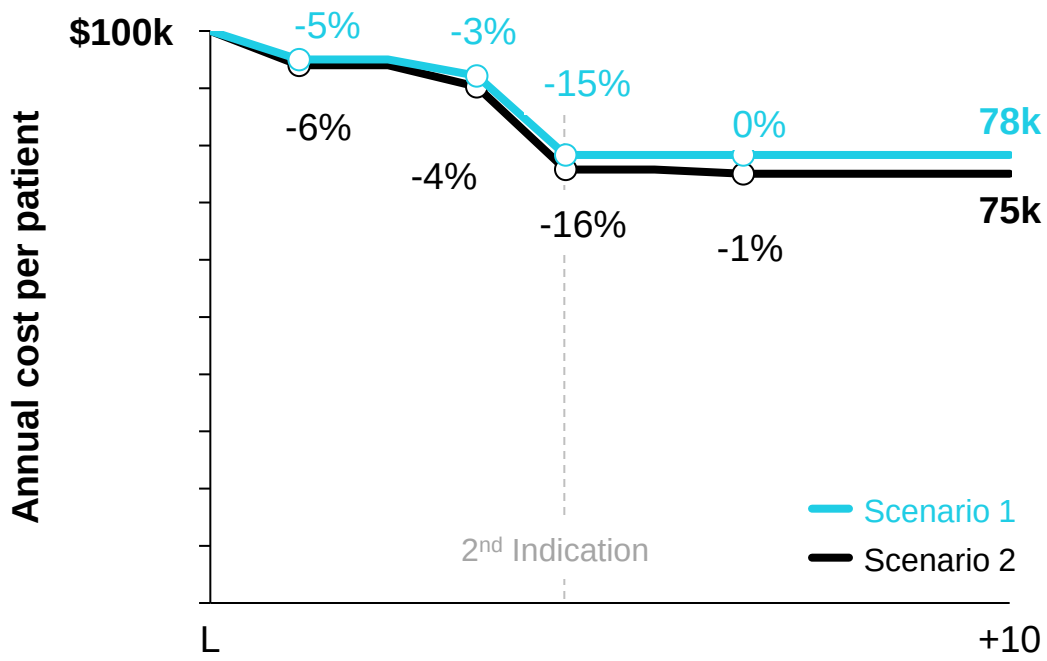
VPAG

Opted in newer medicines subject to 22.9% payback rates in 2025[5]

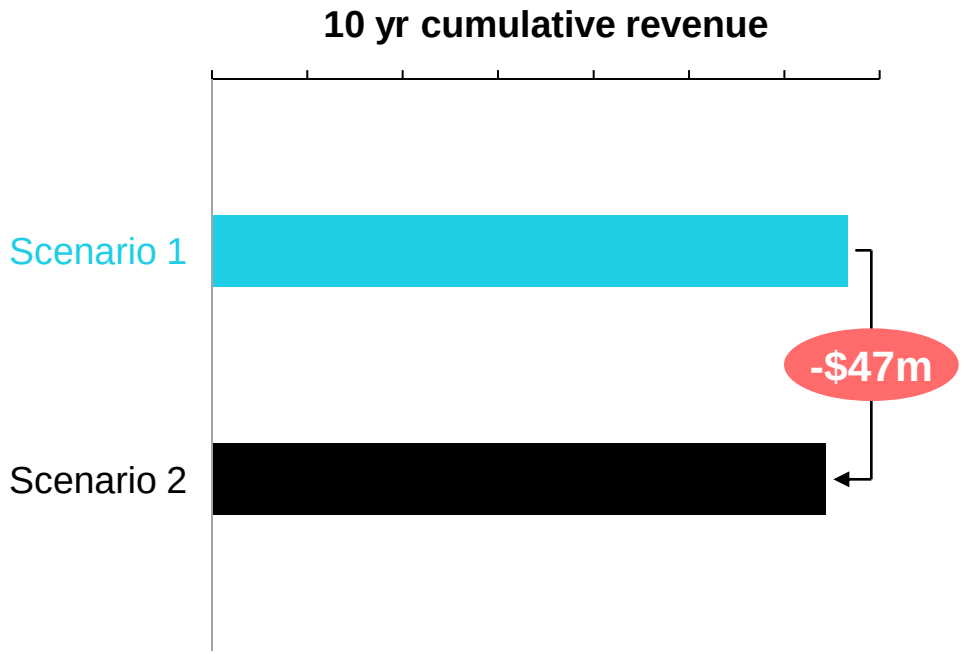
References: 1. OECD. Accessed at: https://www.oecd.org/en/topics/policy-issues/health-spending-and-financial-sustainability.html; 2. Kings Funds. Accessed at: https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/ 3. G-BA German Social Code. Accessed at: https://www.g-ba.de/english/benefitassessment/; 4. APM News; 5. UK Government. 2024 voluntary scheme for branded medicines pricing, access and growth. Abbreviations: CEPS: Economic Committee for Health Products; GDP: Gross domestic product; OECD: Organization for Economic Co-operation and Development; SHI: Statutory health insurance; VPAG: Voluntary scheme for pricing, access and growth

Both launch and life-cycle pricing strategy are critical for sustainable innovation

Post-launch price from launch (L) to L+10



Impact on cumulative revenue



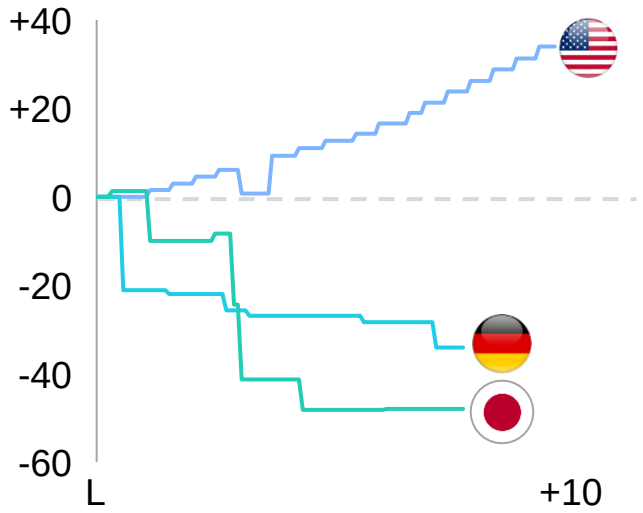
A single percentage point difference in each price erosion event can make a tangible difference

Illustration based on peak annual volume of 1,000 pts with a linear ramp up of 4 years (indication 1) and 2,000 pts with a linear ramp up of 5 years (indication 2). Annual price assumed to be equal across both indications. Market share consistent across scenarios
Abbreviations: k: Thousands; L: Launch

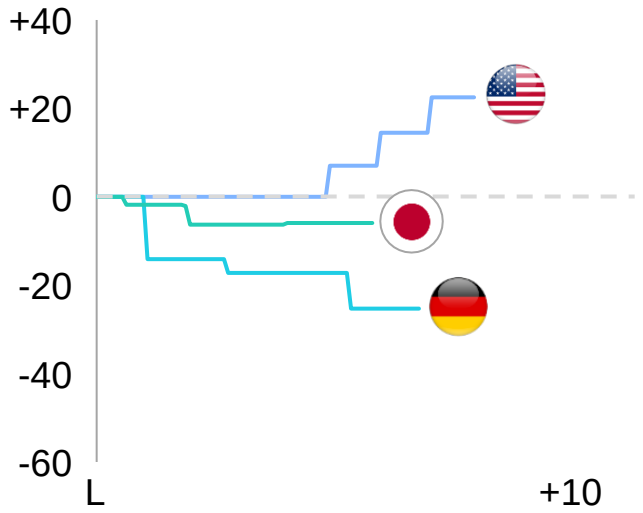
History has shown us the dynamism and volatility of price over the product life cycle

Price evolution as a % vs. launch price (L) to L+10yrs[1]

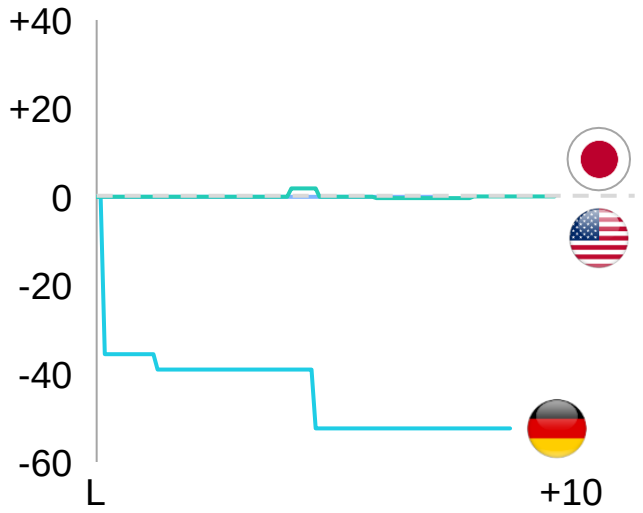
Non-rare Oncology: Keytruda



ATMP in Rare Oncology: Kymriah



Ultra-rare non-oncology: Strensiq

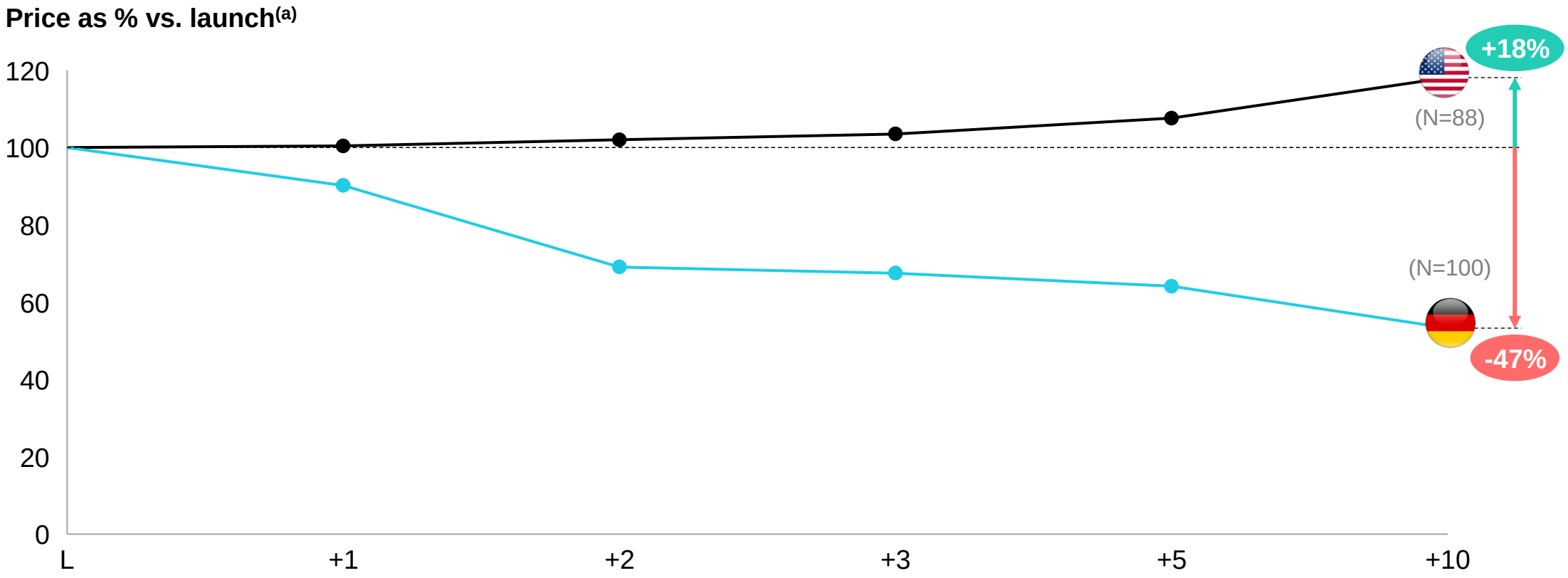


Price change (launch vs. current)			
	34%	**-34%**	**-48%**
	23%	**-25%**	**-6%**
	0%	**-52%**	**0%**

References: 1. Dolon data on file – Global data; Abbreviations: ATMP: Advanced therapy medicinal products; DE: Germany; JP: Japan; L: Launch; US: United States

History has shown us the dynamism and volatility of price over the product life cycle

Price evolution vs. launch price (L) to L+10yrs for a cohort of cancer drugs between 2011-2022[1]



(a) Prices were calculated using dosing information from the FDA label and median treatment duration or truncated at 12mo. For drugs with multiple dosage forms/packages, lowest cost dosage was used. All prices were adjusted for inflation using data provided by the Organisation for Economic Co-operation and Development. References: Laube Y, et al. JAMA Health Forum (2024). Abbreviations: L: Launch

Price over the product life-cycle is influenced by several events

Competitive environment

Pressure from evolving competitor pricing and/or entry of new competitors that change the price benchmarks within an indication

Contract expiry & re-assessments

Requests for pre-planned or ad-hoc renegotiations due to time on market or availability of longer-term follow-up data/RWE

IRP

Changes in reference markets driving new lower international benchmarks or IRP basket average prices

Indication expansion

New indications bringing different value propositions, competitive dynamics and/or an increasing eligible population size to the franchise

Abbreviations: IRP: International Reference Pricing; RWE: Real-world evidence;

The price impact of indication expansions is multi-factorial

Key factors influencing price erosion upon indication expansion

	▲ Greater price erosion	▼ Lower price erosion
Unmet need	Low	High
Political importance	Unknown	Priority
Evidence quality	Single-arm trial	RCT
Added value vs. SoC	Symptomatic	Curative
Increase in eligible population	Negligible	Significant
Use in combination	Brand-on-brand	Monotherapy
Price benchmarks	Gx/BSC	High-cost

Mechanics influencing price evolution upon indication expansion

Lowest indication price applied across all indications

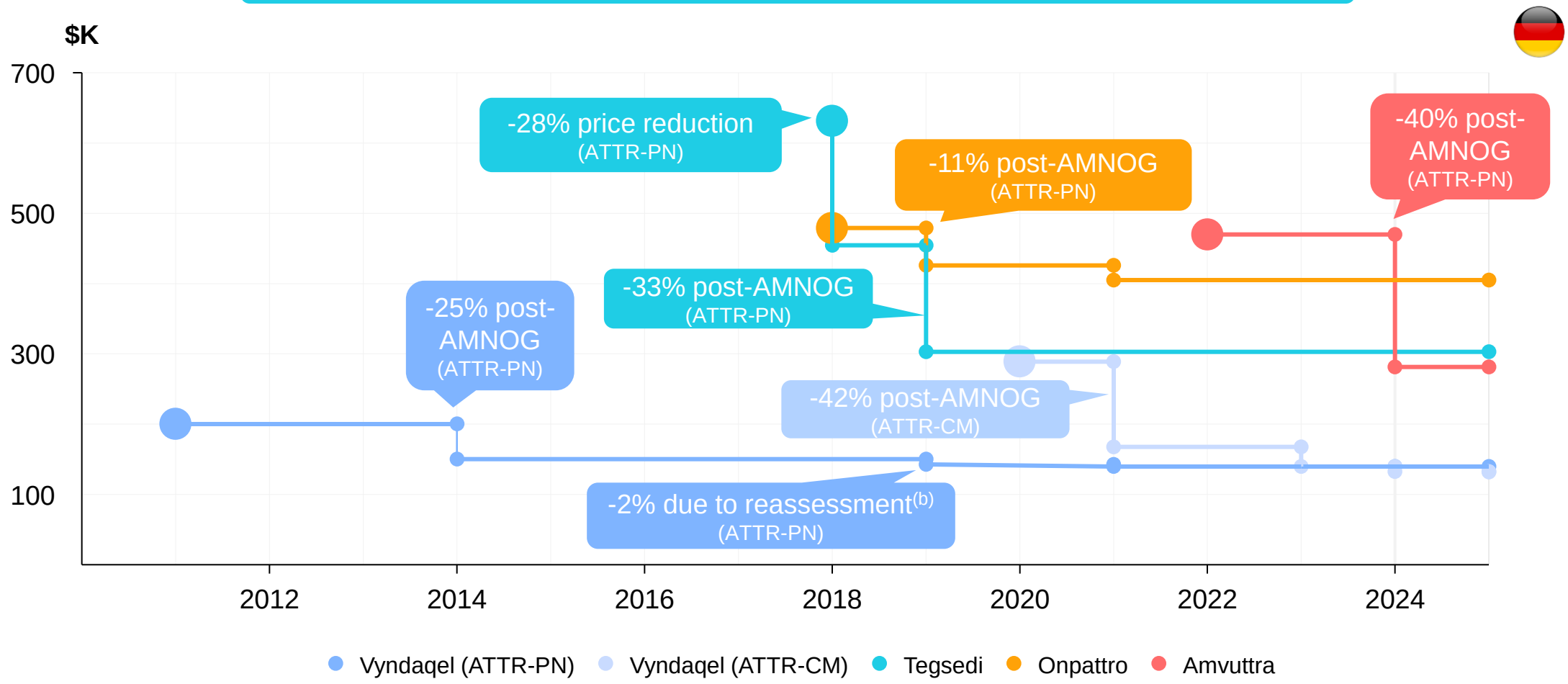
Blended-weighted calculation

Mixed but **volume increase important driver**

Abbreviations: BSC: Best supportive care; Gx: Generics; RCT: Randomised controlled trial; SoC: Standard of care

Understanding the evolution of the competitive space is crucial yet complex

Evolution of ex-factory price per patient per year for ATTR medicines[1(a)]



(a) Current prices reflects the price available on 15th February 2025. (b) Following exceeding of €50M ODD sales threshold. References: 1. Dolon data on file – Pharmazie & Global data; 2. EMA EPAR Reports: Vyndaqel, Tegsedi, Onpattro, Amvuttra. Abbreviations: AMNOG: Arzneimittelmarkt-Neuordnungsgesetz (Pharmaceuticals Market Reorganisation Act); ATTR: Transthyretin amyloidosis; CM: Cardiomyopathy; PN: Polyneuropathy; K: Thousands

Several principles allow us to forecast price effectively

Application to price forecasting

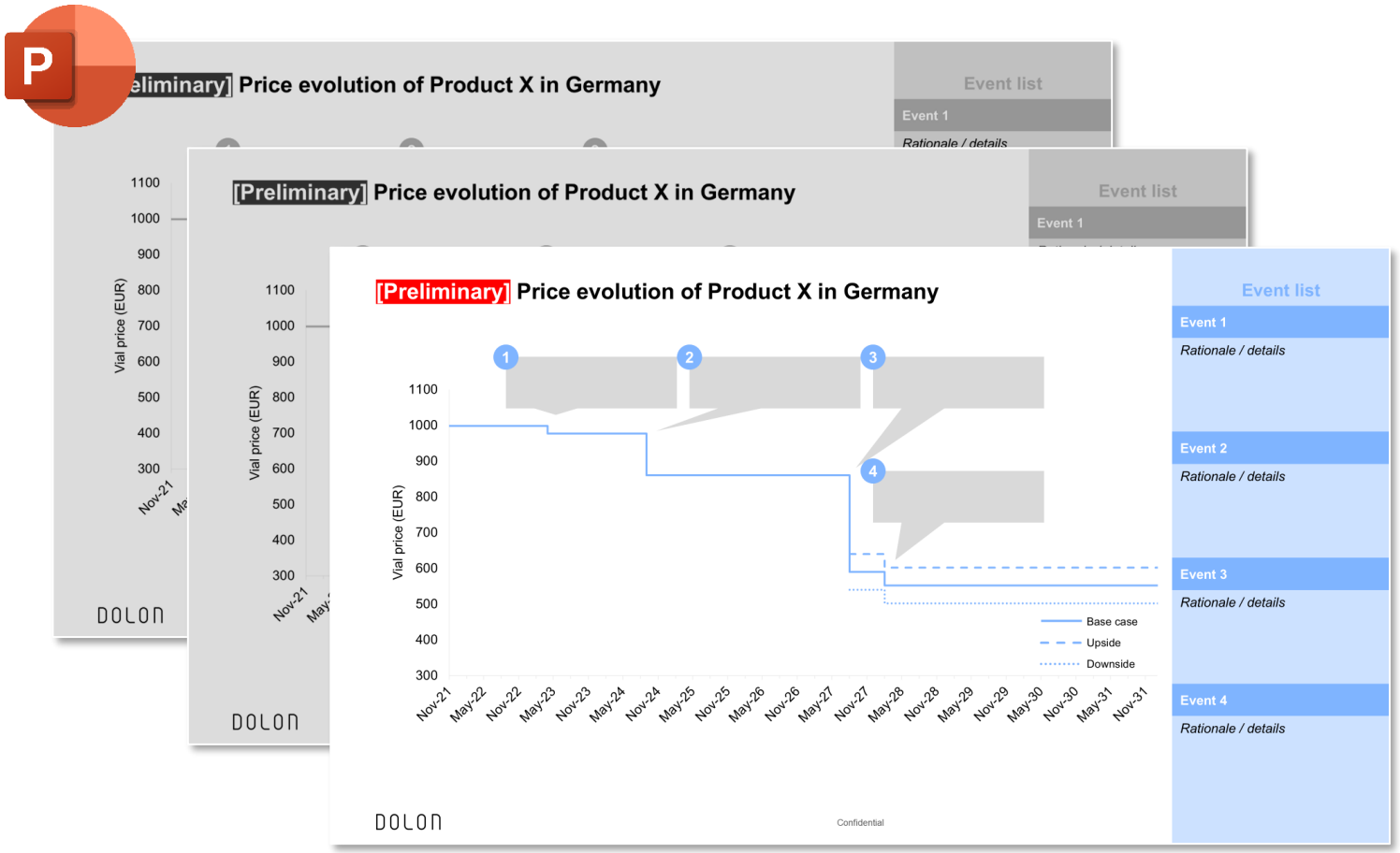
Traits of super-forecasters[1]

Assess the external situation	Review recent P&R decisions and changes to the policy environment before making hypotheses
Think in degrees of uncertainty	Indicate confidence in price assumptions, including upside and downside cases as appropriate
Use multiple sources	Pressure test hypotheses with global, affiliate teams, and primary market research
Expose assumptions	Publish hypotheses in a clear and digestible format so they can be easily validated
Review and revise frequently	Revisit forecasts periodically (e.g., to align with internal budget cycle)
Keep score	Review prior forecasts for accuracy to identify any patterns/errors in underlying assumptions

References: 1. Tetlock & Gardner, 2019 “Superforecasting: The Art & Science of Prediction”; Abbreviations: P&R: Pricing & Reimbursement

Tracking and maintaining price evolution assumptions is a complex undertaking

Using PowerPoint compounds forecasting complexity



Powerpoint pains

Complexity maintaining multiple evolution scenarios

Manual calculations required across many slides

No cascading updates after % price changes

Analytical tools can provide efficiency while maintaining clarity of insight

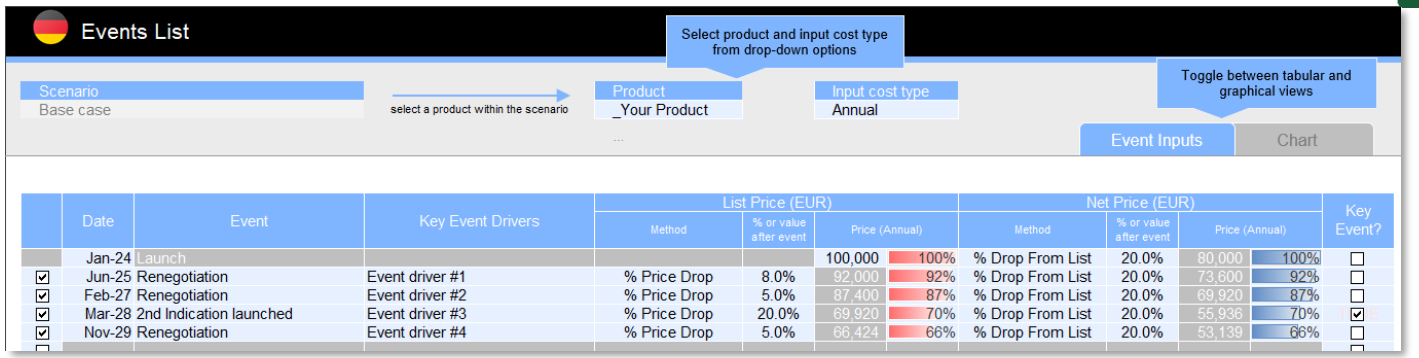
Excel efficiency

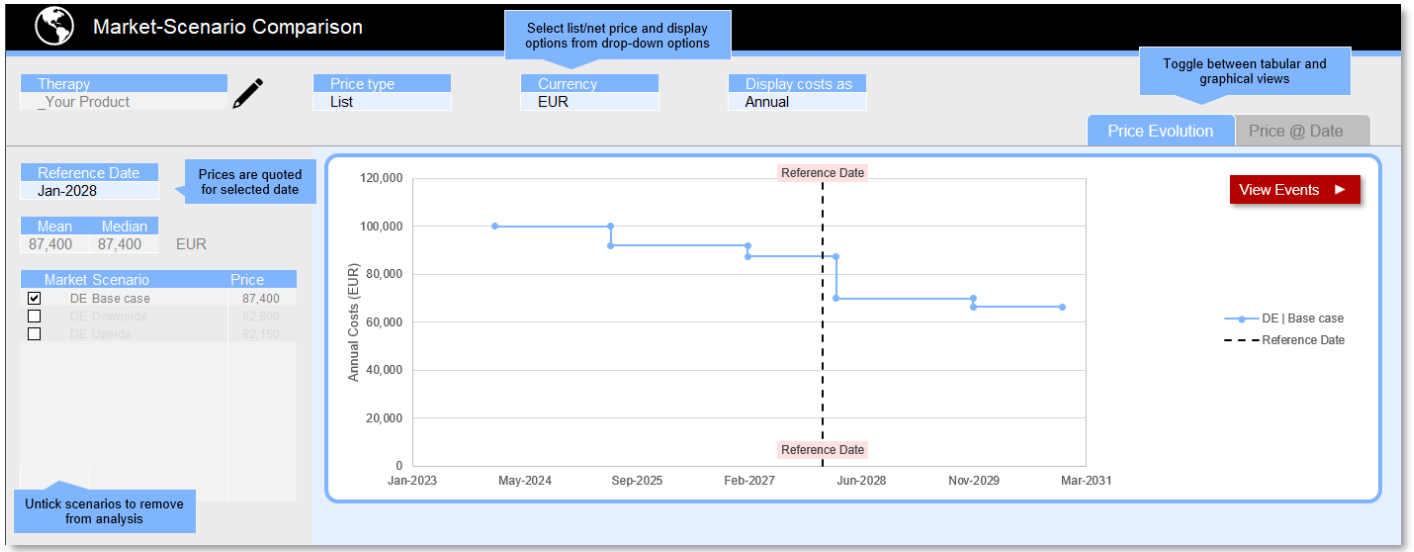
Provides clarity through digestible interfaces

Efficiency gains via cascading updates

Graphical, easy to **interpret outputs**

Pre-formatted Excel templates provide structure



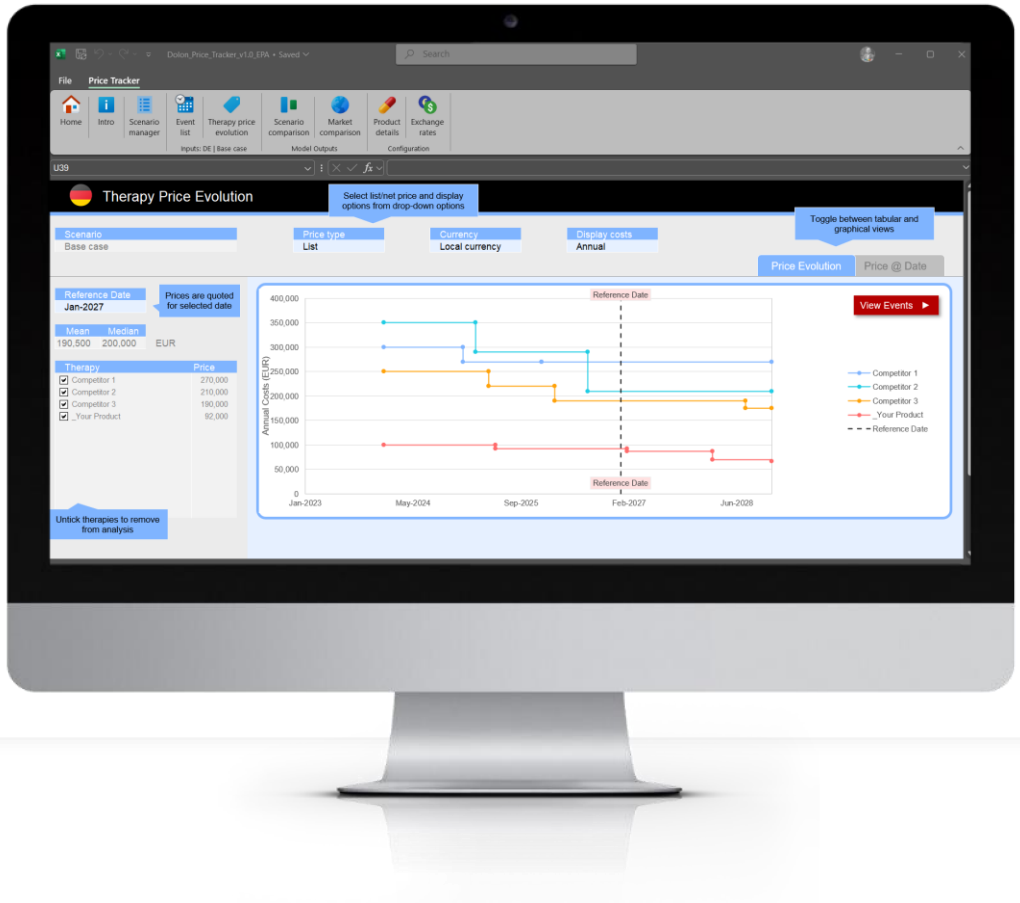


Scenario management effectively captures the inherent complexity of price forecasting

Dolon's Price Evolution Tracker

Maintain a **library of scenarios** each with unique pricing event assumptions

Keep track of **revisions** as pricing assumptions evolve across markets



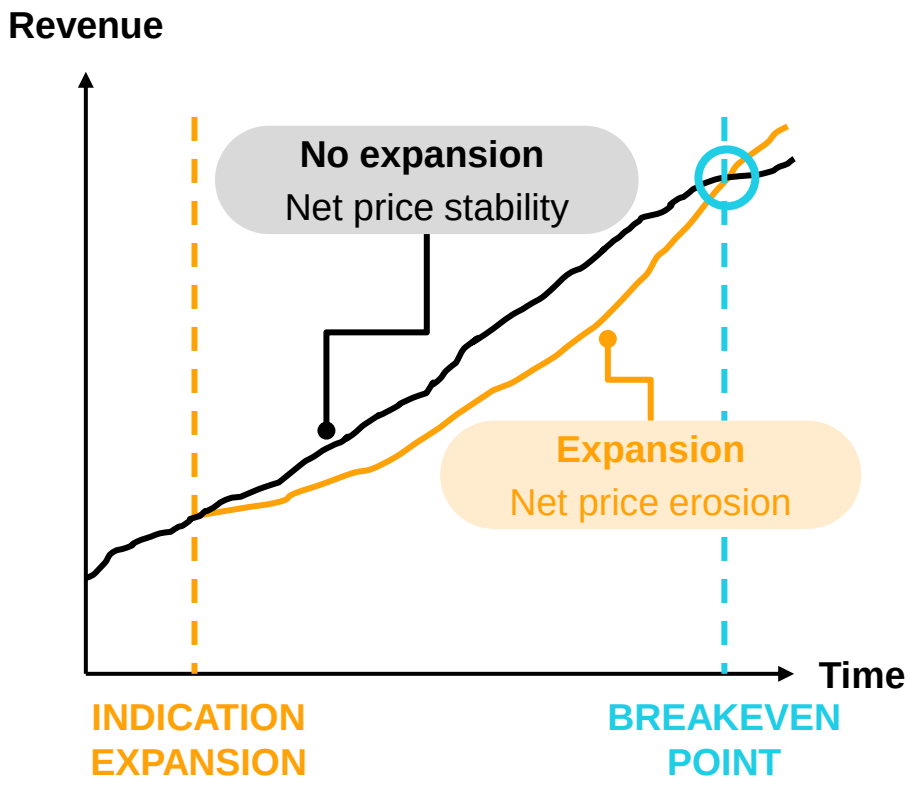
Track your product as well as **competitor pricing** landscape

Review **credibility of forecasts** against actual price evolution

Example screenshots from Dolon's Price Evolution proprietary tool

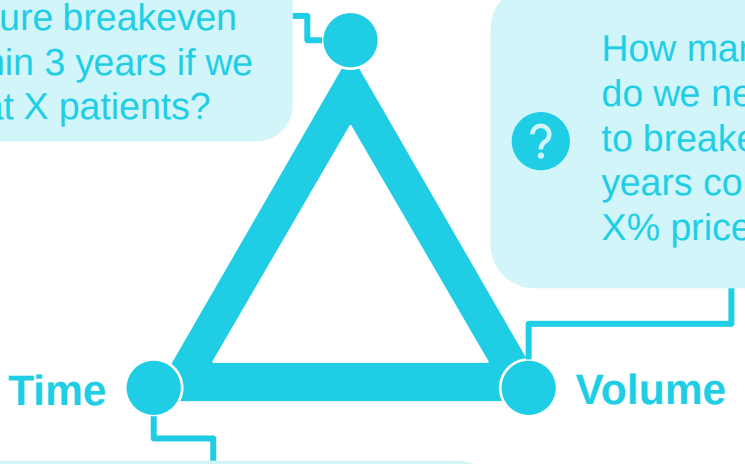
Price forecasting can be used to inform breakeven analyses and strategic decision-making

Cumulative revenue by launch scenario



Breakeven analyses research questions

What is the **max. price erosion** to ensure breakeven within 3 years if we treat X patients?



How many **patients** do we need to reach to breakeven in 3 years considering X% price erosion?

How long will it take to breakeven under specific price erosion and volume assumptions?

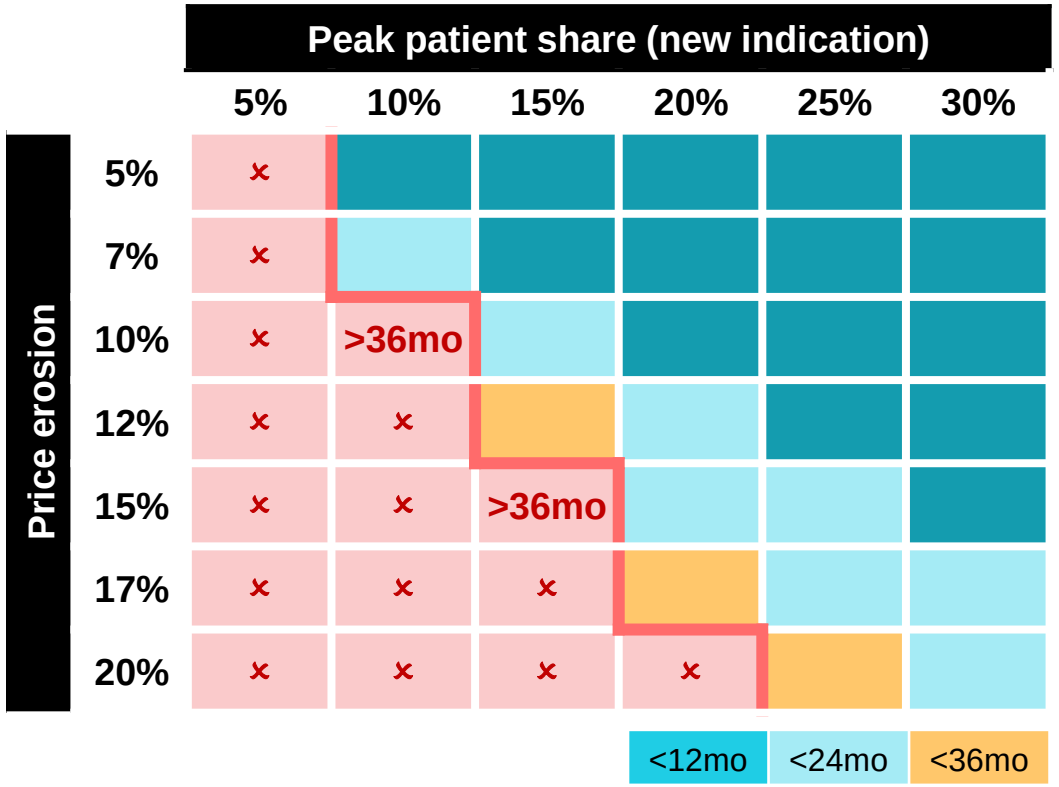
Case study 1: Using breakeven analysis to inform indication expansion strategy for an oncology medicine

Key research question

What combination of price erosion and uptake would mean no 'breakeven' within 3 years of launch (in key markets)?

Analysis (Example market)

Time to breakeven:
Expansion vs. no expansion scenario



Output

Time to breakeven informed pricing guidance for indication expansion

Price forecasts fed into internal (affiliate) budgeting and forecasting process

Abbreviations: mo: Months

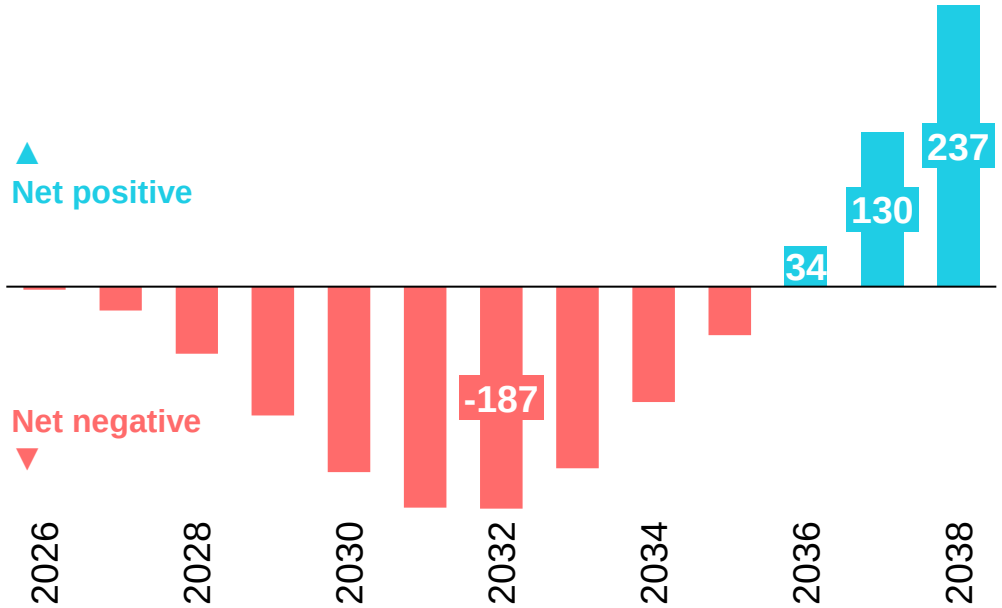
Case study 2: Using breakeven analysis to inform launch timing strategy

Key research question

What would be the impact on mid-term franchise revenue if an indication expansion is delayed to await additional data for negotiations?

Analysis (Regional)

Cumulative net revenue ($):
Delay scenario vs. base case launch timing



Output

Delay scenario expected to become net revenue positive for franchise 10 years after launch

▼

Informed indication expansion decision and price guidance

Conclusions

Price forecasting is essential to robust strategy development