

# BioLink Weekly

Intelligence for Pharma & Biotech Professionals

SPECIAL REPORT · April 2026 · FDA & EMA Drug Approvals 2023–2026

## Make vs. Buy: How Big & Mid-Size Pharma Source Innovation

A four-year analysis of FDA & EMA approved medicines and their development origins (2023–2026)

**Editor's Note:** This report analyses 71 novel drug approvals by Big Pharma MNCs and mid-size pharmaceutical companies across FDA and EMA from January 2023 through April 2026. Each approved medicine is classified as In-House (discovered and developed internally), In-Licensed (rights acquired from an external partner), or Acquired via M&A (the originating company was bought before or after approval). Biosimilars and supplemental indications are excluded.

### DEFINITIONS

#### In-House

Drug discovered and developed entirely within the company's own R&D organisation.

#### In-Licensed

Rights to a drug originated elsewhere, licensed into the company via a partnership or deal — originating company remains independent.

#### Acquired (M&A)

The company that originated the drug was acquired outright, bringing the asset into the acquirer's portfolio.

### YEAR-BY-YEAR BREAKDOWN (FDA + EMA COMBINED)

**2023** — 29 novel approved drugs



**2024** — 18 novel approved drugs



**2025** — 19 novel approved drugs



## OVERALL 2023–2026 TOTALS (71 DRUGS)



## KEY INSIGHTS

### In-House R&D still dominates — but M&A is closing the gap

Across all four years, 59% of approvals (42/71) came from a company's own labs. However, 2024 marked the first year where Acquired-via-M&A deals matched In-Licensed deals at 28% each — driven by BMS's blockbuster acquisitions of Turning Point Therapeutics (repotrectinib / Augtyro), Karuna Therapeutics (xanomeline-trospium / Cobenfy), and Mirati Therapeutics (adagrasib / Krazati). Combined external sourcing (In-Licensed + M&A) reached 56% in 2024, briefly overtaking in-house.

### 2025: A strong internal R&D rebound

2025 reversed the trend sharply. In-house approvals surged to 68% (13/19 drugs), led by Boehringer Ingelheim (nerandomilast, zongertinib), Eli Lilly (imlunestrant), J&J/Janssen (nipocalimab), Regeneron (linvoseltamab), and AstraZeneca (clesrovimab). This suggests that large M&A waves of 2021–2023 have yet to fully flow through the pipeline, and internal programs remain the backbone of approval counts.

### In-licensing increasingly flows from Asia

Of the 16 in-licensed drugs, several reflect a notable China-to-West licensing trend: Takeda's fruquintinib (from HUTCHMED), BMS's tislelizumab (from BeiGene), and several mid-size deals. This mirrors the broader industry data showing large pharma's licensing from Chinese biopharma grew 66% in value between 2023 and 2024.

## COMPANY SPOTLIGHT: WHO BUILDS VS. WHO BUYS

Company	Total Drugs	In-House	In-Lic / M&A	Strategy Summary
Pfizer	6	2	4	Mixed — strong M&A pipeline (Biohaven, Arena, Turning Point) supplements internal engine
Eli Lilly	5	5	0	Predominantly in-house — pirtobrutinib, mirikizumab, kisucla, imlunestrant, orforglipron
Bristol-Myers Squibb	5	0	5	Almost entirely M&A-driven in this period — Karuna, Mirati, Turning Point acquisitions
Boehringer Ingelheim	3	3	0	100% in-house — nerandomilast, zongertinib + Jascayd PPF extension
Sanofi	3	1	2	Mixed — Altuviio (in-house), fitusiran (licensed from Alnylam), rilzabrutinib

				(acq. Principia)
<b>Novartis</b>	<b>3</b>	<b>2</b>	<b>1</b>	Mostly in-house (iptacopan, garadacimab) plus Chinook M&A (atrasentan)
<b>J&amp;J / Janssen</b>	<b>4</b>	<b>4</b>	<b>0</b>	Fully in-house — talquetamab, zenocutuzumab, nipocalimab, plus Bizengri license from Merus
<b>AstraZeneca</b>	<b>3</b>	<b>2</b>	<b>1</b>	Mostly in-house (Abrysvo, Beyfortus, Enflonsia); eplontersen co-developed with Ionis
<b>Roche / Genentech</b>	<b>3</b>	<b>3</b>	<b>0</b>	100% in-house — glofitamab, itovebi, imdelltra
<b>GSK</b>	<b>3</b>	<b>2</b>	<b>1</b>	Mostly in-house (Arexvy, Blujepa, Lynavoy); momelotinib via Sierra Oncology acquisition

## TRENDS TO WATCH

### ► Oral small molecules making a comeback

Despite biologics dominating headlines, small molecules accounted for the majority of approvals in each year. Highlights include the first oral GLP-1 agonist (orforglipron, Lilly), a first-in-class non-opioid pain drug (suzetrigine, Vertex), and first-in-class antibiotics. Oral bioavailability remains a key R&D differentiator.

### ► CRISPR & gene therapy moving from promise to approval

2023 saw the world's first CRISPR-based therapy (Casgevy) gain FDA and EMA approval — a landmark jointly developed by Vertex and CRISPR Therapeutics. Gene therapies for hemophilia B (Durveqtix, Pfizer/Sangamo) followed in 2024. The pipeline suggests more gene therapy approvals are likely in 2026–2027.

### ► RNA therapeutics: siRNA and ASOs gaining ground




Three siRNA or ASO drugs were approved: nedosiran (Novo Nordisk, from Dicerna), eplontersen (AstraZeneca/Ionis), and fitusiran (Sanofi, from Alnylam). All were in-licensed or M&A-driven — suggesting that RNA platform expertise still resides primarily in specialist biotechs rather than large pharma.

### ► GLP-1 competition heats up beyond injectables

Eli Lilly's April 2026 approval of orforglipron — the first approved oral small-molecule GLP-1 agonist — marks a step-change in the obesity/metabolic disease space. Competition from Novo Nordisk and others is expected to intensify through 2026–2028.

## Approvals by Company (Top Companies)

Company	Size	Total	In-House	In-Licensed	Acquired (M&A)
Pfizer	MNC	8	4	4	0
Eli Lilly	MNC	5	5	0	0
Sanofi	MNC	4	1	1	2
GSK	MNC	4	3	0	1
Bristol-Myers Squibb	MNC	4	0	1	3
AstraZeneca	MNC	3	2	1	0
Johnson & Johnson	MNC	3	2	1	0
Biogen	MNC	2	0	1	1
Regeneron	MNC	2	2	0	0
Roche	MNC	2	2	0	0
UCB	MNC	2	2	0	0
Novo Nordisk	MNC	2	0	1	1
Novartis	MNC	2	1	0	1
Vertex Pharmaceuticals	MNC	2	1	1	0
Servier	MNC	2	0	2	0
Madrigal Pharmaceuticals	MNC	2	2	0	0
Daiichi Sankyo	MNC	2	1	0	1
CSL Behring	MNC	2	2	0	0
Otsuka Pharmaceutical	MNC	2	1	0	1
Boehringer Ingelheim	MNC	2	2	0	0
Eisai	MNC	1	1	0	0
Apellis Pharmaceuticals	MNC	1	1	0	0
Genmab	MNC	1	0	1	0
Takeda	MNC	1	0	1	0
Italfarmaco	MNC	1	1	0	0
Idorsia Pharmaceuticals	MNC	1	1	0	0
Ipsen	MNC	1	0	1	0
Gilead Sciences	MNC	1	0	0	1
Amgen	MNC	1	1	0	0
Sun Pharmaceutical Industries	MNC	1	0	0	1
LEO Pharma	MNC	1	1	0	0
Incyte Corporation	MNC	1	1	0	0
Ascendis Pharma	MNC	1	1	0	0
Corcept Therapeutics	MNC	1	1	0	0

COLOR LEGEND:  Green = In-House developed |  Orange = In-Licensed |  Peach = Acquired via M&A (then developed further)

Approvals by Year (Combined FDA + EMA, no double-count per drug)							
Year	Total Drugs	FDA Only	EMA Only	Both FDA+EMA	In-House	In-Licensed	Acquired (M&A)
2023	29	4	1	24	16	9	4
2024	18	8	1	9	8	5	5
2025	19	13	2	4	13	2	4
2026	5	5	0	0	5	0	0
<b>TOTAL</b>	<b>71</b>	<b>30</b>	<b>4</b>	<b>37</b>	<b>42</b>	<b>16</b>	<b>13</b>

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Data sourced from FDA Novel Drug Approvals database, EMA Human Medicines reports, and company press releases (2023–2026). Covers Big Pharma MNCs (revenue >\$10B) and Mid-Size Pharma (\$1B–\$10B). Biosimilars and supplemental indications excluded. Analysis based on 71 novel drug entries.