Top Story

Merck & Co. signals confidence in defending Keytruda beyond 2028 cliff

Anna Bratulic

PUBLISHED : FEBRUARY 03, 2026

Ref: Merck & Co., Reuters

Merck & Co. CEO Rob Davis is signalling growing confidence that Keytruda's US market protection could extend beyond the widely modeled 2028 loss of exclusivity (LOE) — even as the blockbuster cancer drug's annual sales crossed the $30-billion threshold for the first time (see – Spotlight On: Merck & Co.'s fastest selling drugs in 2025).

Speaking on Merck's fourth-quarter earnings call on Tuesday, Davis laid out the structure of Keytruda's patent estate, noting that while the core compound patent expires in December 2028, two other patents — a method-of-making patent running to May 2029 and a method-of-use patent extending to November 2029 — could delay biosimilar entry of the blockbuster cancer immunotherapy.

Emerging case law

"As we looked at this initially, we were conservative in our assumptions and always based off the compound patent…with the intent [though] that we would defend the entire patent estate," Davis said. "What has evolved over time is that, as case law has emerged, our confidence that we will be able to defend those additional two patents has grown, and thus there is a potential that you're going to see protection actually make it through either May or November of 2029."

Why Generics Are Most Exposed to Pricing Transparency Laws

State drug price transparency rules are evolving-now targeting generics, biosimilars, and off-patent drugs. Here's how to navigate the shift in 2026.

SPONSORED BY TWO LABS

1/3 FREE MONTHLY ARTICLES READ

Become a member for access to free articles and newsletters!

Register

Halozyme EX2017
Merck v. Halozyme
IPR2026-00313

not on the list released by the Centers for Medicare & Medicaid Services for the third round of price negotiations last week (see – Vital Signs: The bark may be gone from IRA, but can it still bite?).

Shift to Qlex

Fourth-quarter sales of the intravenous PD-1 inhibitor, along with its recently approved subcutaneous formulation, Keytruda Qlex, totalled close to $8.4 billion, up 7% year over year.

Qlex alone brought in $35 million, though that's likely to climb substantially as time goes on, with nearly 40% of clinicians telling *FirstWord* in a recent poll that they've already started weaving it into routine practice (see – Physician Views Results: Oncologists begin integrating SC Keytruda Qlex, expect meaningful uptake within a year).

Davis said Merck continues to push adoption of Keytruda Qlex, which the company expects to reach 30-40% penetration by 2028. "We have priced this to drive for the adoption from Keytruda IV to Qlex," Davis said, "and frankly, whether [the Keytruda LOE is] '28 or '29 does not change the strategy we're following."

Other Q4 results

In other financial results, Merck said total sales during the fourth quarter of 2025 reached $16.4 billion, an increase of 5% over the same time in 2024. The company saw triple-digit growth with its pulmonary arterial hypertension treatment Winrevair ($467 million, +133%) and 21-valent pneumococcal vaccine Capvaxive ($279 million, +460%), though its Gardasil HPV vaccine continues to experience significant decline ($1 billion, -35%) as driven by lower demand in China and Japan.

Enflonsia, Merck's respiratory syncytial virus (RSV) mAb to protect infants, generated $21 million in the fourth quarter, reflecting a "lower-than-expected" infant passive immunisation rate and high levels of total RSV mAb inventory on the market. Still, doctors appear to like what they've seen so far in the roughly half a year it has been on shelves (see – Physician Views Results: Enflonsia picks up steam but Beyfortus boasts crown as regulators probe safety of RSV antibodies).

Overall group sales in 2025 were up 1% to $65 billion. The company expects sales between $65.5 billion and $67 billion this year, though the higher end of the range falls short of the $67.6 billion analysts were expecting. Merck said it expects a $2.5-billion revenue headwind this year, including from generic competition and IRA price-setting for Januvia, as well as weaker sales of its COVID-19 therapy Lagevrio.

While the fourth-quarter results "build a reasonable foundation for Merck heading into 2026," BMO Capital analyst Evan Seigerman said a lower-than-expected revenue outlook may temper expectations for the year.

Meanwhile, Davis reiterated the $70-billion commercial opportunity he sees for Merck over the next decade, highlighting near-term programmes such as islatravir plus lenacapavir in HIV, long-acting antiviral candidate MK-1406 (CD388) derived from its $9.2-billion Cidara Therapeutics buyout, eye disease drug MK-3000 and TL1A mAb tulisokibart for inflammatory diseases (see – JPM26: Merck & Co. targets $70B in revenues by mid-2030s).

Go Beyond the Story with FirstWord AI

How will Keytruda's patent extensions impact biosimilars?

What is the market outlook for Keytruda Qlex adoption?

How might IRA pricing affect Merck's 2029 revenues?

1/3 FREE MONTHLY ARTICLES READ

Become a member for access to free articles and newsletters!

Merck & Co. Tulisokibart Winrevair

REFERENCE ARTICLES

Merck & Co., Inc., Rahway, N.J., USA Announces Fourth-Quarter and Full-Year 2025 Financial Results; Highlights Progress Advancing Broad, Diverse Pipeline [Merck & Co.]

Merck's 2026 outlook clouds upbeat fourth-quarter results [Reuters]

RELATED NEWS

Top Story

Merck & Co. lifts outlook as Keytruda's Q3 sales top $4.5 billion

OCTOBER 28, 2021

Top Story

Merck & Co.'s sales rise over 20% in Q2, led by Keytruda, vaccines

JULY 29, 2021

Top Story

Merck & Co. sees sales of Keytruda grow 21% in Q3

OCTOBER 27, 2020

Top Story

Merck & Co. posts 5 percent higher drug revenue in Q3 as Keytruda, Gardasil and Bridion continue to lead sales

OCTOBER 25, 2018

Top Story

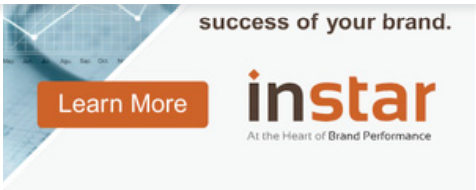
Merck & Co.'s fourth-quarter sales miss estimates

FEBRUARY 02, 2018

VIEW MORE RELATED NEWS

1/3 FREE MONTHLY ARTICLES READ

Become a member for access to free articles and newsletters!



RELATED ANALYSIS

Vital Signs + PLUS

Vital Signs: Winners and losers of the first quarter

READ MORE

Capvaxive CD388 CMS Corporate Affairs Gardasil Islatravir Keytruda Keytruda Qlex Latest Earnings Reports Lenacapavir Merck & Co. Tulisokibart Winrevair

ALL NEWS

Top Story

CRC approval for BMS's Krazati in doubt after confirmatory study miss

16 HOURS AGO

Top Story

Biopharma bites: Novo rebrands Rybelsus as the Ozempic pill, and Amgen trims its pipeline

16 HOURS AGO

People News

Medicines Australia announces new Board Directors

16 HOURS AGO

Press Release

1/3 FREE MONTHLY ARTICLES READ

Become a member for access to free articles and newsletters!

© 2026 FirstWord. All rights reserved | 1140 Avenue of the Americas, 14th Floor, New York, NY 10036

1/3 FREE MONTHLY ARTICLES READ

Become a member for access to free articles and newsletters!