Fresenius

Investor News

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Fresenius and WuXi Biologics enter exclusive development agreement to expand biosimilars pipeline

- Exclusive option rights for up to 37 potential first-to-market biosimilar candidates to significantly expand Fresenius' portfolio from 29 marketed and pipeline molecules today to up to 66 in the next decade, addressing more than €370 billion in originator sales; the largest development agreement announced in the biosimilars industry to date.
- Agreement gives Fresenius full strategic flexibility to select and advance biosimilar candidates to develop, against its established selection criteria, while retaining full commercialization economics of products under the agreement.
- Fresenius will determine the long-term manufacturing strategy for each candidate, with optionality to leverage the mAbxience network, wholly owned since October 2026.
- The next-generation portfolio spans 13 therapeutic areas and multiple biologic technologies, including monoclonal and bispecific antibodies, antibody-drug conjugates and fusion proteins.

Fresenius SE & Co. KGaA (XETR: FRE; OTCM: FSNUY) today announced that it has entered an exclusive development agreement with WuXi Biologics (2269.HK), a leading global contract organization for research, development and manufacturing. WuXi Biologics brings proven large-scale biologics development and manufacturing capability, a track record across monoclonal and bispecific antibodies and antibody-

drug conjugates, and a worldwide network spanning Europe, the United States, China and Singapore. The agreement significantly expands and accelerates Fresenius' biosimilars pipeline while preserving strategic flexibility and disciplined capital allocation. It provides access to a scalable pathway to increase the portfolio from 29 marketed and pipeline molecules today to up to 66 molecules, addressing more than €370 billion in originator list-price-based-sales, extending Biopharma growth in the long term beyond its 2030 ambition.

The agreement provides Fresenius with exclusive access to up to 37 identified biosimilar candidates over the next decade, making it the largest development agreement announced in the biosimilars industry to date. Development programs will be selected and advanced against Fresenius' established selection criteria, based on market attractiveness, development risk, and expected returns. Fresenius will hold exclusive global commercialization rights, including marketing authorizations, and the full economics of each commercialized product under the agreement.

Michael Sen, Chief Executive Officer of Fresenius, said: "We are doubling down on our Biopharma business. With this agreement we are gaining access to development capabilities in a market where speed and scale are of the essence. It provides a disciplined, scalable way to potentially triple our portfolio while retaining economic ownership, strategic control and the flexibility to allocate capital to the most compelling opportunities. Combined with the full ownership of mAbxience, this fuels our Biopharma growth well beyond 2030."

The next-generation portfolio is expected to span 13 therapeutic areas, including expanding into neurology, nephrology and cardiopulmonary, while further strengthening Fresenius' established positions in oncology, immunology, and gastroenterology. It will encompass multiple biologic technologies, including monoclonal and bispecific antibodies, antibody-drug conjugates and fusion proteins. Initial development is expected to focus on polatuzumab vedotin, an antibody-drug conjugate for the treatment of diffuse large B-cell lymphoma, and teprotumumab, a monoclonal antibody for the treatment of thyroid eye disease.

The agreement forms part of a balanced pipeline expansion strategy through internal R&D, targeted collaboration, and selective in-licensing. It gives Fresenius privileged access to the rapidly advancing biotech landscape worldwide and combines this with Fresenius' global manufacturing and commercialization network. Development activities are expected to be conducted using WuXi Biologics' global network. Building on the recent acquisition of Spain-headquartered mAbxience, the agreement

significantly expands the funnel of potential development candidates for Fresenius' wholly owned platform, enabling greater value capture across the development, manufacturing and commercialization value chain.

Financial Considerations

Fresenius' full-year 2026 guidance remains unchanged, and the Company confirms the 2030 Biopharma ambition announced in December 2025 of – approximately doubling Biopharma revenue compared with 2025 at an EBIT margin of around 20% – which relates to the existing marketed and late-stage portfolio. The agreement is additive, expanding the opportunity beyond 2030, and, as a result, Fresenius expects to raise its long-term Biopharma ambitions significantly.

Under the terms of the agreement, Fresenius will compensate WuXi Biologics on a fee-for-service basis for each biosimilar candidate that Fresenius selects for development. Research and development investment scales only as selected programs progress, with each option exercised against Fresenius' established selection criteria (market attractiveness, development risk, and expected returns). Fresenius will determine the long-term manufacturing strategy for each biosimilar candidate, including the potential progressive transfer of selected products to mAbxience. Fresenius will hold exclusive global commercialization rights, including marketing authorizations, and the full economics of each commercialized product under the agreement.

As selected candidates advance, Biopharma research and development expenditure and profitability will correspondingly reflect the increased level of investment during the development phase, ahead of future revenue and profitability growth.

The agreement fits within Fresenius' unchanged financial framework, with continued priority on a strong balance sheet and further deleveraging; it is funded from operating cash flow and requires no new financing. Fresenius is rated BBB with a positive outlook by S&P, Baa3 with a stable outlook by Moody's, and BBB- with a positive outlook by Fitch.

Related Publications

The 1 October 2026 announcement of Fresenius' acquisition of the remaining 45% of mAbxience is available here. The 31 March 2022 announcement of Fresenius Kabi's acquisition of a 55% majority stake in mAbxience is available here, and the 1 August 2022 completion announcement here. The Biopharma 'Meet the Management' presentation of 15 December 2025 is available here.

About polatuzumab vedotin

Polatuzumab vedotin is an antibody-drug conjugate (ADC) marketed under the brand name Polivy® for the treatment large B-cell lymphoma (DLBCL), the most common subtype of non-Hodgkin lymphoma.[1]
Globally, DLBCL accounts for approximately one-third of non-Hodgkin lymphomas.[2] In 2024, more than 562,000 new cases of non-Hodgkin lymphoma were diagnosed worldwide, with approximately 235,000 deaths attributed to the disease.[3]
The polatuzumab vedotin ADC comprises a monoclonal antibody directed against CD79b, a protein expressed on B cells including DLBCL cells, linked to the microtubule-disrupting agent monomethyl auristatin E (MMAE) through a cleavable linker. Following binding to CD79b, the ADC is internalized and MMAE is released, disrupting microtubules and leading to cell death.[1]
Polivy® is administered by intravenous infusion and is a registered trademark of Genentech, Inc.

About teprotumumab

Teprotumumab is a human monoclonal antibody marketed under the brand name Tepezza® for the treatment of thyroid eye disease (TED), a rare autoimmune condition associated with Graves' disease.[4] TED is estimated to affect approximately 16 women and 3 men per 100,000 people annually, with around 25-50% of patients with Graves' disease developing signs and symptoms of TED.[5]

Teprotumumab binds to and inhibits the insulin-like growth factor-1 receptor (IGF-1R), a receptor involved in cellular signaling pathways associated with the development and progression of TED. By inhibiting IGF-1R signaling, teprotumumab helps reduce the inflammatory and tissue-remodeling processes associated with the disease. Tepezza® is administered by intravenous infusion and is a registered trademark of Amgen Inc.

References

[1] Polivy® (polatuzumab vedotin-piiq) U.S. Prescribing Information. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761121s008lbl.pdf [Last accessed October 2026].

[2] Wang, S. S. (2023) Epidemiology and Etiology of Diffuse Large B-Cell Lymphoma (DLBCL). *Semin. Hematol.* 60, 255–266.

[3] International Agency for Research on Cancer. Global Cancer Observatory: Non-Hodgkin Lymphoma Fact Sheet, GLOBOCAN 2024. Available at: https://gco.iarc.who.int/media/globocan/factsheets/cancers/34-non-hodgkin-lymphoma-fact-sheet.pdf [Last accessed October 2026]

[4] Tepezza® (teprotumumab-trbw) U.S. Prescribing Information. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761143s012lbl.pdf [Last accessed October 2026].

[5] Moledina, M., Damato, E. M. & Lee, V. (2024) The changing landscape of thyroid eye disease: current clinical advances and future outlook. *Eye* 38, 1425-37.

About Fresenius

Fresenius SE & Co. KGaA (XETR: FRE; OTCM: FSNUY) is a global healthcare company headquartered in Bad Homburg vor der Höhe, Germany. In the full-year 2025, Fresenius generated €22.6 billion (excluding special items) in annual revenue. Fresenius employs more than 178,000 people. The Fresenius Group comprises the operating companies Fresenius Kabi and Fresenius Helios as well as an investment in the separately listed Fresenius Medical Care AG.

With around 140 hospitals, 330 outpatient facilities and 300 occupational risk prevention centres, Fresenius Helios is the leading private hospital operator in Germany and Spain, treating around 27 million patients every year. Fresenius Kabi's product portfolio touches the lives of 450 million patients annually and includes a range of highly complex biopharmaceuticals, clinical nutrition, medical technology, and intravenous generic drugs and fluids.

Fresenius was established in 1912 by the Frankfurt pharmacist Dr. Eduard Fresenius. After his death, Else Kröner took over management of the company in 1952. She laid the foundations for a global enterprise that today pursues the goal of improving people's health. The largest shareholder is the non-profit Else Kröner Fresenius Foundation, which is dedicated to advancing medical research and supporting humanitarian projects.

For more information, visit fresenius.com and follow Fresenius Investor Relations on LinkedIn.

About Fresenius Medical Care

Fresenius Medical Care AG is an independent, separately listed company (XETR: FME; NYSE: FMS), in which Fresenius SE & Co. KGaA holds a financial investment of approximately 25%; Fresenius Medical Care's results are not consolidated in the Fresenius Group's revenue and earnings.

Forward-Looking Statements

This release contains forward-looking statements that are subject to various risks and uncertainties including statements regarding the potential number of biosimilar candidates developed under the agreement with WuXi Biologics, the resulting pipeline size (including references to "up to 66" molecules), the timing and scope of any transfer of manufacturing to the mAbxience network, and Fresenius' growth prospects beyond 2030. Whether, when and how many candidates are developed under the agreement remains subject to Fresenius' future exercise of options on a candidate-by-candidate basis, and no assurance can be given that any, or all, of the identified candidates will be developed or will reach the market. Future results could differ materially from those described in these forward-looking statements due to certain factors, e.g. changes in business, economic and competitive conditions, regulatory reforms, results of clinical trials, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings, the availability of financing and unforeseen impacts of international conflicts. Fresenius does not undertake any responsibility to update the forward-looking statements in this release.

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Securities Information
Fresenius SE & Co. KGaA is listed on the Frankfurt Stock Exchange and is a member of the DAX 40 index. The shares are traded on Xetra, the electronic trading venue of Deutsche Börse, under the ticker FRE.
ISIN: DE000FRE5EN2 ● German Securities Code: FRE5EN

American Depository Receipts
Fresenius SE & Co. KGaA maintains a sponsored Level I American Depositary Receipt programme, traded over the counter in the United States on the OTC Markets platform under the ticker FSNUY, at a ratio of four American Depositary Receipts to one ordinary share. Depositary bank: J.P. Morgan Chase Bank N.A.
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