



Kyverna Therapeutics and ElevateBio Enter into Commercial Manufacturing and Supply Agreement for Miv-cel

July 27, 2026

New agreement secures flexible and scalable manufacturing to support the U.S. commercial and global clinical supply of miv-cel

EMERYVILLE, Calif., and WALTHAM, Mass., July 27, 2026 (GLOBE NEWSWIRE) -- Kyverna Therapeutics, Inc. (Nasdaq: KYTX), a late-stage clinical biopharmaceutical company developing cell therapies for patients with autoimmune diseases, and ElevateBio, a technology-driven advanced therapy contract development and manufacturing organization (CDMO), today announced a manufacturing agreement for both U.S. commercial and global clinical supply of miv-cel (mivocabtagene autoleucel), Kyverna's autologous CD19-directed CAR T-cell therapy.

The new agreement provides Kyverna with flexible and scalable supply of miv-cel, supporting the Company's potential launches in stiff person syndrome (SPS) and generalized myasthenia gravis (gMG), as well as other ongoing clinical studies. Over the past three years, Kyverna and ElevateBio have built a strong clinical-stage partnership, delivering a track record of success in process development, quality systems, and cell product manufacturing optimization, supporting the SPS Biologics License Application (BLA) and laying the foundation for future growth.

"Kyverna's highest priority is to bring the transformative potential of miv-cel to patients, and this agreement with ElevateBio further strengthens our commercialization readiness and long-term manufacturing supply as we prepare for launch in stiff person syndrome and future indications," said Mayo Pujols, Chief Technology Officer of Kyverna. "With ElevateBio's proven expertise in manufacturing innovation and quality, demonstrated by a clinical manufacturing success rate of more than 98% for miv-cel, as well as their ability to scale production, we're pleased to continue to advance our partnership."

Kyverna remains on track to complete the rolling BLA submission for miv-cel in SPS in the fourth quarter of 2026. If approved, miv-cel has the potential to become the first FDA-approved CAR T-cell therapy for an autoimmune disease and the first approved treatment for people living with SPS.

"This agreement affirms ElevateBio's commitment to the commercial supply of miv-cel and highlights the quality of our partnership with Kyverna," said Chris Murphy, Chief Executive Officer of ElevateBio. "By combining our technology and manufacturing expertise with Kyverna's leadership in autoimmune cell therapies, we are well-positioned to deliver reliable supply that supports patients today and growing demand in the years ahead."

About miv-cel (mivocabtagene autoleucel, KYV-101)

Miv-cel is a fully human, autologous, CD19-targeting CAR T-cell therapy with CD28 co-stimulation, designed for potency and tolerability, which is under investigation for B-cell-driven autoimmune diseases. With a single administration, miv-cel has potential to achieve deep B-cell depletion and immune system reset to deliver durable drug-free, disease-free remission in autoimmune diseases.

About Kyverna Therapeutics

Kyverna Therapeutics, Inc. (Nasdaq: KYTX) is a late-stage clinical biopharmaceutical company focused on liberating autoimmune patients through the curative potential of cell therapy. Kyverna's lead autologous CD19-targeting CAR T-cell therapy candidate, miv-cel (mivocabtagene autoleucel, KYV-101), has demonstrated the potential to fundamentally change the treatment paradigm across multiple B-cell-driven autoimmune diseases. Kyverna is advancing its potentially first-in-class neuroimmunology franchise with its recently completed registrational trial in stiff person syndrome (SPS) and an ongoing registrational trial for generalized myasthenia gravis. The Company has initiated its rolling Biologics License Application submission for SPS with the FDA. It is also harnessing other KYSA trials and investigator-initiated trials, including in multiple sclerosis and rheumatoid arthritis, to inform the next priority indications. Additionally, its next-generation pipeline includes CAR T-cell therapies deploying novel innovations to improve patient access and experience. For more information, please visit <https://kyvernatx.com>.

About ElevateBio

ElevateBio is a technology-driven advanced therapy contract development and manufacturing organization (CDMO) powering the creation of life-transforming therapies. The Company helps biopharmaceutical partners design, develop, and manufacture therapies from early discovery through commercialization, combining proprietary gene editing technologies and discovery services, cGMP manufacturing capabilities, and industry-leading expertise to accelerate development across a breadth of therapeutic approaches and modalities. Through continuous investment in automation, AI, and next-generation technologies, ElevateBio delivers the quality, speed, and scale partners need to bring advanced therapies to more patients. For more information, visit www.elevatebio.com.

Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements." The words, without limitation, "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these or similar identifying words. Forward-looking statements in this press release include, without limitation, those related to: Kyverna's next phase of growth and potential long-term growth, including its transition to a commercial-stage organization; any potential FDA approval and commercial launch of miv-cel in SPS; Kyverna's pipeline opportunities and strategic priorities; Kyverna's potentially first-in-class neuroimmunology franchise; Kyverna's rolling BLA SPS submission and expected timeline for completion thereof; the possibility that miv-cel will be the first FDA-approved CAR-T cell therapy for an autoimmune disease and the first approved treatment for people living with SPS; Kyverna's potential to advance curative treatments for patients and any anticipated demand therefor; the expected benefits of the manufacturing and supply agreement with ElevateBio, including its ability to provide reliable supply of miv-cel and support Kyverna's potential launches in SPS, gMG and other ongoing clinical studies, and to scale production and further strengthen Kyverna's commercialization readiness and long-term manufacturing supply; the quality of ElevateBio's manufacturing and its partnership with Kyverna; and miv-cel's potential to fundamentally change the treatment paradigm across multiple B-cell-driven autoimmune diseases, and to achieve deep B-cell depletion and immune system reset to deliver durable drug-free, disease-free remission in autoimmune diseases. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties related to market conditions, the possibility that results from prior clinical trials, named-patient access activities and preclinical studies may not necessarily be predictive of future results; the possibility that the past track records of Kyverna or ElevateBio may not be repeated or indicative of future success; and other factors discussed in the "Risk Factors" section of Kyverna's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q that Kyverna has filed or may subsequently file with the U.S.

Securities and Exchange Commission. Any forward-looking statements contained in this press release are based on the current expectations of Kyverna's management team and speak only as of the date hereof, and Kyverna specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

Kyverna Contacts:

Investors: InvestorRelations@kyvernatx.com

Media: media@kyvernatx.com

ElevateBio Contacts:

Investor contact:

Catherine Hu

chu@elevate.bio