Vivesto receives Orphan Drug Designation in the U.S. for Cantrixil in AML

Solna, Sweden, November 3, 2026 – Vivesto AB, an oncology-focused development company, today announces that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to Cantrixil for the treatment of people with acute myeloid leukemia (AML). The designation provides access to potential incentives during development, as well as the possibility of market exclusivity following approval.

The FDA's decision is based on its assessment that AML qualifies as a rare disease in the United States and that there is a scientific rationale for the use of Cantrixil in AML. AML is an aggressive form of blood cancer with a significant need for new treatment options. In 2026, an estimated 22,720 people in the United States will be diagnosed with AML, and about 11,500 will die from the disease.[1]

"The Orphan Drug Designation is an important regulatory milestone for the development of Cantrixil. It gives us development incentives in the U.S. and the possibility of seven years of market exclusivity upon approval. Together with the positive preclinical results generated to date, the designation strengthens the foundation for advancing Cantrixil toward a Phase I study in AML" says Erik Kinnman, CEO of Vivesto.

Cantrixil is currently in preclinical development for AML. Vivesto has previously reported positive preclinical results demonstrating anti-cancer activity of Cantrixil, both as monotherapy and in combination with established cancer treatments. Moreover, a phase 1 study with Cantrixil has previously been done. The recent preclinical and previous clinical results support the continued development of Cantrixil toward clinical studies in patients with AML.

The FDA grants Orphan Drug Designation to drug candidates intended for the treatment, prevention or diagnosis of rare diseases or conditions affecting fewer than 200,000 people in the United States. The designation provides potential development incentives, including tax credits for qualifying clinical trials and exemption from certain regulatory application fees. If Cantrixil receives FDA marketing approval for the designated indication and applicable requirements are met, it may also qualify for seven years of market exclusivity in the United States.

Orphan Drug Designation does not constitute marketing approval or establish the safety or efficacy of Cantrixil in AML.

1 National Cancer Institute, SEER Cancer Stat Facts: Acute Myeloid Leukemia (2026 estimates). https://seer.cancer.gov/statfacts/html/amyl.html. Accessed November 2, 2026.

For More Information:

Erik Kinnman, Chief Executive Officer
Phone: +46 018-50 54 40
E-mail: IR@vivesto.com

About Vivesto AB

Vivesto is a Swedish development company that aims to offer new treatment options for hard-to-treat cancers where there are major medical needs and significant market potential. The project portfolio consists of Cantrixil, which is being developed for blood cancer, and the veterinary oncology program Paccal Vet (paclitaxel micellar), which is being evaluated in a pilot clinical trial in dogs with splenic hemangiosarcoma following splenectomy and in a dose-finding study in cats with solid tumors. Vivesto's shares are traded on Nasdaq Stockholm (ticker: VIVE). Visit www.vivesto.com for more information about Vivesto.

About Cantrixil

Cantrixil (TRX-E-002-1) is a small-molecule drug candidate currently in preclinical development for AML. The candidate has previously been evaluated in a clinical development program in ovarian cancer. Promising preclinical findings in AML provide the rationale for its continued development in this indication.

About Acute Myeloid Leukemia

Acute myeloid leukemia (AML) is an aggressive cancer of the blood and bone marrow and the most common type of acute leukemia in adults. In 2026, an estimated 22,720 people in the United States will be diagnosed with AML, and about 11,500 will die from the disease. The five-year relative survival rate is 33.4%. Despite advances in care, there remains a significant need for new treatment options.[1]

Attachments

Vivesto receives Orphan Drug Designation in the U.S. for Cantrixil in AML