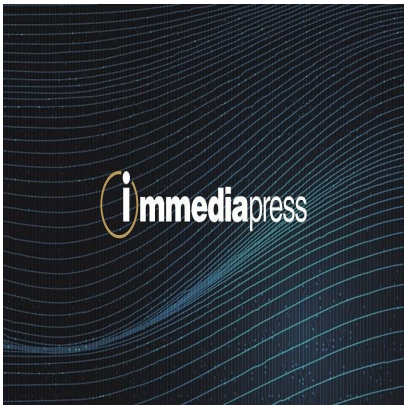

Norgine welcomes positive CHMP opinion recommending approval of mavorixafor in the European Union for WHIM syndrome

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

CHMP recommendation marks major step toward first authorised treatment for WHIM syndrome in EuropeFinal decision expected from the European Commission in Q2 2026 Partnership with X4 Pharmaceuticals for Norgine-led commercialisation in Europe

AMSTERDAM, Feb. 27, 2026 /PRNewswire/ â?? Norgine B.V., a leading European specialty pharmaceutical company, today welcomes the positive opinion issued by the European Medicines Agencyâ??s (EMA) Committee for Medicinal Products for Human Use (CHMP) recommending the granting of a marketing authorisation under exceptional circumstances[*] for XOLREMDIÂ® (mavorixafor) in patients aged 12 years and older for the treatment of WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes.[1]

This CHMP positive opinion is an important regulatory milestone for patients living with WHIM syndrome for whom there is currently no other licensed treatment option.[2] The condition results from dysfunction of the chemokine receptor (CXCR4), which impairs the release of white blood cells from the bone marrow into circulation, leading to recurrent and/or severe infections.2

The European Commission (EC) will now review the CHMP recommendation, with a final decision expected in Q2, 2026.

â??We are pleased to see this important regulatory milestone for patients living with WHIM syndrome,â?• said Janneke van der Kamp, Chief Executive Officer, Norgine. â??At Norgine, we have built deep expertise in delivering rare and specialty medicines across Europe, Australia and New Zealand and the positive CHMP opinion for mavorixafor reflects the type of innovation our organisation is designed to bring to patients in need.â?•

The CHMPâ??s positive opinion for mavorixafor is supported by results from the pivotal, phase 3 clinical trial (4WHIM), a global, randomised, double-blind, placebo-controlled, 52-week multicentre study that evaluated the efficacy and safety of mavorixafor in 31 people aged 12 years and older diagnosed with WHIM syndrome.[3]

Norgine and X4 Pharmaceuticals entered into a licensing and supply agreement in January 2025, under which Norgine will commercialise mavorixafor in Europe, Australia and New Zealand following regulatory approval. All marketing authorisations in the licensed territories will be transferred to Norgine. Once completed, Norgine will be responsible for all market access and commercialisation activities in the licensed territories. X4 will manufacture and supply mavorixafor to Norgine.

About WHIM Syndrome

WHIM syndrome is an ultra-rare, combined primary immunodeficiency and chronic neutropenic disorder caused by CXCR4 receptor dysfunction that results in impaired mobilisation of white blood cells from the bone marrow into peripheral circulation. WHIM syndrome is named for its four classic manifestations: warts, hypogammaglobulinemia, infections, and myelokathexis, although only a minority of patients experience all four manifestations. People with WHIM syndrome characteristically have low blood levels of neutrophils (neutropenia) and lymphocytes (lymphopenia), and as a result, experience serious and/or frequent infections.2

About Mavorixafor

Mavorixafor is a selective CXC chemokine receptor 4 (CXCR4) antagonist that binds to the CXCR4 receptor, preventing its interaction with CXCL12,1 which is currently approved in the United States under the trade name XOLREMDIÂ® for the treatment of WHIM syndrome.3

About Norgine

Norgine is a mid-sized EU-based pharmaceutical company with 1,500 employees, generating approximately $650 million in annual sales. At Norgine, innovation drives our mission to deliver medicines that change lives. From common conditions like constipation to rare and severe diseases such as childhood cancer, we target unmet medical needs because we believe that every scientific breakthrough deserves to reach patients in need.

We use our innovative development, commercialisation and manufacturing capabilities as well as strategic partnerships to navigate complex pathways. Combined with our extensive history and deep regional expertise, this approach allows us to accelerate and expand the reach of life-changing medicines across Europe, Australia, and New Zealand.

We are guided by the trust that healthcare professionals and patients place in us and remain committed to delivering innovation that transforms lives, one patient at a time.

[*] EMA definition for Exceptional Circumstances: A type of marketing authorisation granted to medicines where the applicant is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because the condition to be treated is rare or because collection of full

information is not possible or is unethical.

[1] XOLREMDIÂ® (mavorixafor) CHMP opinion[2] WHIM Syndrome â?? Symptoms, Causes, Treatment | NORD, accessed February 2026[3] Badolato R, Alsina L, Azar A, et al. A phase 3 randomized trial of mavorixafor, a CXCR4 antagonist, for WHIM syndrome. Blood. 2024;144(1):35â??45.

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Categoria

1. Comunicati

Tag

1. ImmediaPress

Data di creazione
Febbraio 27, 2026
Autore
redazione