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X4 Pharmaceuticals Announces EMA Validation of Marketing Authorization Application (MAA) for Mavorixafor - licenced to Norgine for commercialisation in Europe.

London (ots/PRNewswire) -

Following the licensing agreement with X4 Pharmaceuticals, Norgine is pleased to see the announcement from X4 today that their Marketing Authorization Application (MAA) for mavorixafor for the treatment of WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis), a rare primary immunodeficiency, has been validated for review and is now under evaluation with the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP). In April 2024, mavorixafor received U.S. Food and Drug Administration approval as XOLREMDI®, an oral, once-daily treatment for use in patients 12 years of age and older with WHIM syndrome.

Norgine is working with X4 to enable access to mavorixafor for patients in Europe, Australia and New Zealand and this regulatory milestone is an important step toward this goal.

About X4 Pharmaceuticals

X4 is delivering progress for patients by developing and commercializing innovative therapies for those with rare diseases of the immune system and significant unmet needs. Leveraging expertise in CXCR4 and immune system biology, X4 has successfully developed mavorixafor, an orally available CXCR4 antagonist that is currently being marketed in the U.S. as XOLREMDI® in its first indication. The company is also evaluating additional uses of mavorixafor and is conducting a global, pivotal Phase 3 clinical trial (4WARD) in people with certain chronic neutropenic disorders. X4 is headquartered in Boston, Massachusetts and operates a research center of excellence in Vienna, Austria.

About Norgine

Norgine is a uniquely positioned, specialty pharmaceutical and consumer healthcare company, with more than €500 million of annual revenues and a 120-year track record of bringing life-changing products to patients and consumers across their core markets of Western Europe, Australia, and New Zealand. Today's Norgine is a nimble, innovative, and high-performing company that has been transformed by a relentless focus on operational excellence to do the right thing by patients, push boundaries, and take strides into new therapeutic areas. The company's integrated approach – strong commercial capabilities, deep medical, regulatory and clinical expertise, in-house manufacturing, robust supply networks, and best-in-class enabling functions – ensures delivery of high-quality, transformative medicines quickly and effectively to more than 25 million patients annually.

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