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Medivir's Cold Sore Treatment Xerese™ Now Launched in the United States

Huddinge, Sweden - Medivir AB (OMX: MVIR), the emerging research-based specialty pharmaceutical company focused on infectious diseases, today announces that the Company's commercialization partner, Meda AB, has launched Medivir's unique cold sore treatment Xerese™ in the United States.

Xerese™ is the first topical combination product of five per cent acyclovir and one per cent hydrocortisone in a unique cream vehicle for the treatment of recurrent herpes simplex labialis. Xerese™ was granted FDA marketing approval [1] and based on strong clinical data, Xerese™ was given a label, which differentiates it from other topical cold sore products currently on the market.[2] Xerese™ will be sold in the U.S. as a prescription medicine.

Medivir estimates that the U.S. market for cold sore products is valued at USD 230 million (EUR 168 million) and with Meda's strong commercial presence and deep understanding of U.S. market dynamics, combined with Xerese's™ differentiated profile, it is anticipated that Xerese™ will be a successful entrant to the cold sore treatment market. Medivir granted Meda the exclusive rights to market, sell and distribute Xerese™ in the United States, Canada and Mexico for the treatment of cold sores (herpes labialis) in February 2010. In addition to funding the commercial development of Xerese™ and up-front and pre-launch milestones totaling USD 5 million, Medivir will also receive double-digit royalties on sales.

Ron Long, CEO of Medivir, commented: "We are delighted that Xerese™ has been launched on the U.S. market today. Our partner Meda has a strong commercial presence in the US and has demonstrated great success in marketing products in the U.S., specifically in dermatology. We very much look forward to the further launches of Xerese™ by our partner Meda in Canada and Mexico and also the launch later this year in Europe by our partner GlaxoSmithKline."

About Xerese™ (Xerclear® in Europe)
Xerese™ is the first and only cold sore treatment that demonstrated greater efficacy vs. 5% acyclovir in the same cream vehicle (with early treatment), reduced the likelihood of progression to ulceration with early treatment [3] and combines an antiviral and an anti-inflammatory.

Xerese™ also provided faster healing time vs. vehicle placebo (mean time to skin normalization was approximately 1.6 days shorter) [4], 50% greater reduction in cumulative lesion area with Xerese™ vs. vehicle placebo and greater relief of symptoms, such as tenderness vs. vehicle placebo [3],[4].

About cold sores

Recurrent herpes labialis (cold sores) is a common infection that affects one-third of the population in the Western world resulting in around 600 million episodes per year with 57 million people having 3 or more episodes per year. The great majority of cases are caused by herpes simplex virus type 1 (HSV-1). Unlike most viruses, the cold sore virus is not completely eliminated by the body's immune response. Instead it establishes a chronic, latent and life-long infection in sensory ganglia. At a later date, the virus may be reactivated and travel back to the skin – often around the mouth and nose – to trigger a clinical episode of recurrent herpes labialis. The virus is reactivated by factors like sunlight and stress.

Products based on antiviral substances such as aciclovir, penciclovir, famciclovir and valaciclovir are the most commonly used treatment options. The market for topical treatment of herpes infections in the USA and Europe is estimated at USD 230 million and USD 170 million, respectively.

References:

[1] US Food and Drug Administration, 31/07/2009.

www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist

[2] US Food And Drug Administration, 5/12/2010.

www.accessdata.fda.gov/drugsatfda_docs/label/2010/022436s001lbl.pdf

[3] Hull CM, Harmenberg J, Arlander E, et al. Early treatment of cold sores with topical ME-609 decreases the frequency of ulcerative lesions: a randomized, double-blind, placebo-controlled, patient-initiated clinical trial [published online ahead of print September 17, 2010].

[4] Xerese™ (package insert). Somerset, NJ:Meda Pharmaceuticals Inc.; 2010

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About Medivir

Medivir is an emerging research-based specialty pharmaceutical company focused on the development of high-value treatments for infectious diseases. Medivir has world class expertise in polymerase and protease drug targets and drug development which has resulted in a strong infectious disease R&D portfolio. The Company's key pipeline asset is TMC435, a protease inhibitor which has recently entered phase 3 clinical development for hepatitis C and is partnered with Tibotec Pharmaceuticals.

Medivir is also marketing its first product, the unique cold sore product Xerese™/Xerclear® which has recently been launched on the US market. Xerese™/Xerclear®, which has been approved in both the US and Europe. is partnered with GlaxoSmithKline to be sold OTC in Europe, Japan and Russia and with Meda AB in North America, Canada and Mexico. Medivir has retained the Rx rights for Xerclear® in Sweden and Finland.

For more information about Medivir, please visit the Company's website: www.medivir.com.