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For immediate release

## GlaxoSmithKline enters agreement with Medivir for exclusive rights to cold sore treatment Xerclear™

GlaxoSmithKline (GSK) and Medivir (STO: MVIR-B) today announced an exclusive agreement for the commercialisation of cold sore treatment, Xerclear™ (acyclovir and hydrocortisone) for non-prescription use (OTC) in key global markets. Xerclear is the first and only topical herpes labialis (cold sores) treatment clinically proven to help prevent cold sore lesions appearing.<sup>i</sup>

Under the terms of the agreement, GSK gains exclusive rights to commercialise and distribute non-prescription Xerclear™ as part of the Zovirax™ franchise, across multiple markets, including Europe, Russia, Japan, India, Australia and New Zealand. The agreement excludes North and South America, China, South Korea and Israel.

GSK will assume responsibility for funding ongoing and future commercial development of Xerclear™ in all territories covered by the agreement. In addition to funding the commercial development of Xerclear™, GSK will pay up to Euro 3 million in up-front and pre-launch milestones and up to double-digit royalties on sales to Medivir for the exclusive rights.

John Clarke, President, Consumer Healthcare GSK, said: "This alliance demonstrates GSK's ongoing commitment to invest in and expand our OTC business. It will help strengthen our dermatology portfolio across multiple territories including several key emerging markets. "

"We are pleased to have partnered Xerclear™ with GlaxoSmithKline Consumer Healthcare – one of the world's largest OTC consumer healthcare products companies, said Ron Long, Medivir's CEO, and concluded, "This represents a major step in the global commercialisation of our cold sore product."

Xerclear™, a combination product of acyclovir and hydrocortisone - was granted marketing approval in 14 European countries in October 2009. Based on strong clinical data, Xerclear™ was given a unique label, which differentiates it from other topical cold sore products currently on the market.<sup>ii</sup>

### About Xerclear™

Xerclear™ (Xerese™ in the USA) – a patented combination of 5% acyclovir and 1% hydrocortisone in Medivir's proprietary cream formulation - is a topical product for the treatment of recurrent herpes labialis. The indication text as approved in Europe states " *Treatment of early signs and symptoms of recurrent herpes labialis (cold sores) to **reduce the progression of cold sore episodes to ulcerative lesions** in immunocompetent adults and adolescents (12 years of age and older)*" Xerclear™ is the first topical product that in controlled clinical trials has been shown to significantly (P<0.0001 vs. placebo) reduce the development of ulcerative lesions during a cold sore episode.

## **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.

Today only 1-2% of the episodes are treated. 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 are estimated to USD 230 million and USD 170 million, respectively.

## **About Medivir**

Based on its world class expertise in protease and polymerase inhibition technology, Medivir develops drugs with primary focus on infectious diseases. Its objective is to become a sustainable and profitable speciality pharmaceutical company with a strong research base.

Medivir's first pharmaceutical product - for the topical treatment of cold sores - has recently been approved by the US FDA (trademark "Xerese™") and in Europe (trademark "Xerclear™"). The product will be commercialized through partners outside the Nordic region, where Medivir intends to market and sell the product.

Medivir was listed on the Stockholm Stock Exchange in 1996 and at the end of 2009 the company had 85 employees.

## **About GlaxoSmithKline**

**GlaxoSmithKline** is one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit [www.gsk.com](http://www.gsk.com)

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## **References**

<sup>1</sup>Hull, C. Episodic treatment with topical ACV/Hydrocortisone prevents cold sores: A randomized, double-blind, patient-initiated clinical trial. Poster presentation 49th ICAAC meeting in San Fransisco, USA (2009) and data on file.

<sup>2</sup> Xerclear SPC, approved 2009-10-14, [www.mpa.se](http://www.mpa.se)