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MIKA Pharma and GALENpharma report mutual development of tarenflurbil spray for dermatology

Ludwigshafen/Kiel, December 12, 2008. - MIKA Pharma GmbH, a leading German drug delivery company, and GALENpharma GmbH, Germany's market leader in the field of topical corticosteroids, today announced that they will co-operate on the development of MIKA´s tarenflurbil spray (patent protected until 2020) for dermatology. GALENpharma will finance the development until completion of a phase III proof-of-concept trial and receives in return the exclusive licence rights for Germany. Earnings out of down payments and licence fees from third parties out of other territories will be shared between MIKA and GALENpharma.

Tarenflurbil (R-flurbiprofen) is an inhibitor of the inflammation related activation of the transcription factor NFkappaB, which governs the activation of inflammation related genes, such as cyclooxygenase 2 (COX-2) and cytokine genes. Corticosteroids, which are at present mainly used for the treatment of inflammatory skin diseases, act via such an inhibition of the NFkappaB activation pathway. However, corticosteroids have other effects as well and may cause severe side effects especially when used in the therapy for chronic diseases. Tarenflurbil has been proven in many clinical trials to be a very safe and well tolerated active. Therefore, tarenflurbil spray offers the potential to become a new and safe treatment option for common skin diseases, such as atopic dermatitis. Tarenflurbil spray is developed to replace corticosteroids in skin therapy and combines a most promising new active with MIKA´s well established and innovative topical drug delivery technology.

About Tarenflurbil
Tarenflurbil (R-flurbiprofen) is considered the "inactive" isomer of the nonselective COX inhibitor S-flurbiprofen, because it does not inhibit cyclooxygenase (COX) activity. Nevertheless, Tarenflurbil exhibited antinociceptive and antiinflammatory activity in paw inflammation models in rats (1, 2). Interestingly, it was shown that R-flurbiprofen effectively inhibits NFkappaB activation and the transcription of several NF-kappaB-dependent genes such as COX-2. The observed antinociceptive and antiinflammatory effects of R-flurbiprofen are mediated by inhibition of NFkappaB (3). This is particularly interesting because tarenflurbil is regarded as an extraordinary safe drug and has not been reported for the typical side effects of NSAIDs, such as gastrointestinal ulcerations, and might therefore be useful for the treatment of patients who are dependent on long-term therapy in pathologies that involve NFkappaB activation.

About MIKA Pharma GmbH
MIKA Pharma GmbH was established in 1994 for the development and production of primarily dermal, transdermal, and buccal application systems for pharmaceuticals on the basis of sprayable liposomes, pre-liposomal solutions and proprietary micellar nano-solutions. The overall MIKA Pharma GmbH portfolio contains products and advanced projects in various indication fields, e.g. sports injuries, rheumatic disorders, pain, superficial thrombophlebitis, cough, fungal infections, various skin disorders, to mention just a few. For additional information about the company, please visit http://www.mika-pharma.de .

About GALENpharma GmbH

GALENpharma GmbH has started more than 20 years ago to offer medical products and treatment concepts in dermatology. Today GALENpharma is one of Germany's leading companies in this field. For additional information about the company, please visit http://www.galenpharma.de .

Literature

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