Versatis® as effective as pregabalin in the treatment of localised neuropathic pain

Aachen, Germany, 03 June 2009. A clinical study published in *Current Medical Research and Opinion* suggests that Versatis® (5 % lidocaine medicated plaster) monotherapy offers comparable efficacy in the treatment of localised neuropathic pain to pregabalin monotherapy.¹

Patients included in the study suffered from post-herpetic neuralgia (PHN) or diabetic polyneuropathy (DPN). Overall, 65.3 % of the patients treated with Versatis® and 62.0 % of patients receiving pregabalin were considered as responding to pain therapy. Within DPN, efficacy was similar for both treatments. In patients with PHN, Versatis® showed improved efficacy compared with pregabalin. In addition, Versatis® provided a more favourable efficacy/safety profile with greater improvements in patient satisfaction and quality of life than pregabalin for both indications, supporting its first line position in the treatment of localised neuropathic pain.

Neuropathic pain is a challenging and difficult to treat condition. Many patients suffer from neuropathic pain for a long time before they are correctly diagnosed and receive appropriate treatment. Even then, physicians often struggle to adequately manage neuropathic pain, as response to therapy differs from patient to patient. In addition, many treatment options are typically associated with debilitating side effects, which require patients and physicians to compromise between efficacious dosing and limiting side effects that are detrimental to the patients’ quality of life.

“The results of this study show that topical treatment with 5 % lidocaine medicated plaster is an effective treatment option for patients suffering from localised neuropathic pain”, said Ralf Baron, MD, Division of Neurological Pain Research and Therapy, Department of Neurology, University hospital Schleswig-Holstein, Campus Kiel, Germany, lead author of the publication. “Especially interesting are the results in PHN as they indicate for the first time that a topical treatment can be equivalent in the relief of localised neuropathic pain conditions to a systemic treatment.”

**Versatis® vs. pregabalin**

The study recently published in *Current Medical Research and Opinion* investigated the efficacy of Versatis® (5 % lidocaine medicated plaster) monotherapy compared to pregabalin monotherapy in 88 patients suffering from
PHN and 193 patients suffering from painful DPN (per protocol set, PPS). In PHN more patients (62.2 %) responded to treatment with Versatis® than to pregabalin (46.5 %). Response was comparable for patients with painful DPN: 66.7 % (Versatis®) vs. 69.1 % (pregabalin). In addition, Versatis® offered a better tolerability profile which resulted in a lower rate of drug-related adverse events and related discontinuation rates.

“Apart from confirming the high efficacy of Versatis, the new data clearly shows the value of the targeted local approach for the patients’ quality of life”, said Dr Harald F. Stock, Chief Executive Officer of Grünenthal.

Treatment with Versatis® improved quality of life, which was assessed using the EuroQol-5 dimension quality of life index (EQ-5D) estimated health state, to a greater extent than pregabalin in both indications.

Combination therapy of Versatis® and pregabalin
The study also investigated if patients who were not sufficiently responding to monotherapy could benefit from a combination therapy of Versatis® and pregabalin. After four weeks of monotherapy these patients received combination therapy while patients who were adequately responding to monotherapy continued their previous treatment.2

Patients continuing on monotherapy demonstrated additional clinically relevant decreases of their NRS-3 score (pain intensity over the last 3 days on the 11-point numerical rating scale). Patients receiving combination therapy achieved clinically relevant reduction in NRS-3 values in addition to improvement achieved during 4 weeks of monotherapy. Combination therapy was safe and well tolerated. Moreover, when Versatis® was added to pregabalin, the pregabalin dose could be reduced in most of the patients.

About Versatis®
Versatis® lidocaine medicated plaster is registered in many European, Latin American and Middle Eastern countries. Within the European Union, Versatis is currently licensed in Belgium, France, Germany, Luxembourg, Slovenia, Sweden and the UK for the symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN). Guidelines recommend topical lidocaine as a first line treatment for neuropathic pain.3,4

About Grünenthal
Grünenthal is an expert in pain therapy and gynaecology and a pioneer in intelligent, user-friendly drug delivery technologies. The company discovers, develops, produces and markets high therapeutic value pharmaceuticals that contribute to
patients’ ability to control their own lives. Grünenthal is an independent, family-owned German company with companies in 32 countries all over the world. Founded in 1946, the company employs 1,900 people in Germany and 5,300 worldwide. In 2007, Grünenthal achieved revenues of 846 million Euros. More information: www.grunenthal.com