

RECEIVED

FILE NO: 82-4406

2004 OCT -5 P 2 23

From: Antje Witte

CORPORATE COM

Tel: +49 2173 48 1866

OFFICE OF INTERNATIONAL CORPORATE FINANCE Alfred-N

Fax: +49 2173 48 1856

40789 Monheim, Germany

E-mail: antje.witte@schwarzpharma.com

Internet: www.schwarzpharma.com



04045346

SUPPL

September 29, 2004

SCHWARZ PHARMA Submits Marketing Applications for its Rotigotine Patch 'Neupro'

New Drug Application (NDA) and Marketing Authorization Application (MAA) for *Neupro*TM (rotigotine transdermal system) to treat Parkinson's disease submitted to the U.S. and the European regulatory authorities for review.

SCHWARZ PHARMA announced today that applications for marketing approval for the rotigotine transdermal system, a patch, to treat patients in early stages of Parkinson's disease have been submitted to both, the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA).

*Neupro*TM, with the active ingredient rotigotine, is a novel dopamine receptor-agonist formulated as a continuous transdermal delivery system, a patch. The patch is applied once a day to the skin and administers rotigotine transdermally to the body for 24 hours. Multinational clinical studies with patients in early stages of Parkinson's disease were completed at the end of 2003. More than 1,500 patients with Parkinson's disease have been treated with *Neupro*TM (rotigotine transdermal system) in 15 clinical trials.

"This is an important milestone for our company. We are a step closer delivering on our strategy – to develop and to market innovative drugs in the areas of neurology and urology", said Patrick Schwarz-Schütte, CEO SCHWARZ PHARMA AG. "Neupro' has been proposed as the worldwide brand name for our patch."

"This is the first submission of a novel new chemical entity from our innovative pipeline," Iris Loew-Friedrich, MD, PhD, Member of the Executive Board SCHWARZ PHARMA AG said. "The rotigotine team has worked diligently to bring the project to this significant achievement. With many advanced clinical development projects in our pipeline, we are looking forward to the NDA and MAA submissions to come."

juw 10/6

PROCESSED

OCT 06 2004

THOMSON
FINANCIAL

NEWS

Sept. 29, 2004

Page 2 of 2

Parkinson's disease is a disorder of the central nervous system. The patients - roughly four million worldwide - suffer from a lack of dopamine, a messenger substance in the central nervous system, which is responsible for the co-ordination of movement. As a result of this shortage, patients are no longer able to control their movements reliably. Dopamine agonists attempt to compensate for this lack of dopamine.

SCHWARZ PHARMA develops innovative drugs with focus on neurology and urology. There are currently seven projects in clinical development. Also in the last stage of development, phase III are harkoseride to treat epilepsy and neuropathic pain and fesoterodine for the treatment of urinary incontinence. Rotigotine transdermal system is also being studied in phase III trials for treatment of advanced stages of Parkinson's disease and Restless Legs Syndrome (RLS).

SCHWARZ PHARMA AG (headquartered in Monheim, Germany) develops and markets innovative drugs for unmet medical needs with focus on neurology, urology and cardiovascular diseases. The company is investing in development projects targeting diseases such as Parkinson's disease, Restless-Legs-Syndrome, epilepsy, neuropathic pain, overactive bladder syndrome and benign prostatic hyperplasia. The company has a strong international presence with subsidiaries in Europe, USA and Asia. Shares of SCHWARZ PHARMA AG are traded on the Frankfurt and Duesseldorf stock exchanges.

For more information, please see our website: www.schwarzpharma.com
Corporate Communications: Antje Witte, Tel: +49 2173 48 1866

This press release contains forward-looking statements based on current plans, estimates and beliefs of the management of SCHWARZ PHARMA AG. Such statements are subject to risks and uncertainties that may cause actual results to be materially different from those that may be implied by such forward-looking statements contained in this press release. *Important factors that could result in such differences include: changes in general economic, business and competitive conditions, effects of future judicial decisions, changes in regulation affecting SCHWARZ PHARMA AG, exchange rate fluctuations and hiring and retention of its employees.*