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Re: Schwarz Pharma AG (File No. 82-4406)

SUPPL

By UPS

Dear Sir or Madam:

Enclosed herewith is the following document, furnished on behalf of Schwarz Pharma AG (File No. 82-4406) (the "Company"), pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934:

- 1. Press Release, dated June 23, 2004.

This information is being furnished under paragraph (b)(1)(iii) of Rule 12g3-2, with the understanding that such information will not be deemed "filed" with the SEC or otherwise subject to the liabilities of Section 18 of the Exchange Act, and that neither this letter nor the furnishing of such documents and information shall constitute an admission for any purpose that the Company is subject to the Securities Exchange Act of 1934.

Please do not hesitate to contact me at 212-506-2604 in connection with this matter. Thank you for your assistance.

Sincerely,  
*Sharon Purcell*  
Sharon N. Purcell

*dlw*  
*6/30*

Encl

cc: Sylvia Heitzer  
Schwarz Pharma AG  
Philip O. Brandes  
Reb D. Wheeler

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Independent Mexico City Correspondent: Jauregui, Navarrete, Nader y Rojas, S.C.

Mayer, Brown, Rowe & Maw LLP operates in combination with our associated English limited liability partnership in the offices listed above.

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June 23, 2004

## **SCHWARZ PHARMA Presented Phase III Data in Early Parkinson's Disease**

**Pivotal Phase III data on Rotigotine, the Parkinson Patch, presented at the 8<sup>th</sup> International Congress of Parkinson's Disease and Movement Disorders (MDS), June 13 – June 17, 2004, Rome, Italy**

The results of a multinational, randomized, placebo-controlled phase III trial to investigate efficacy, tolerability and safety of rotigotine in patients with early stage Parkinson's disease have been presented at the MDS-Conference in Rome, Italy.

Rotigotine CDS is a novel dopamine receptor-agonist for the treatment of Parkinson's disease formulated as a continuous delivery system, a patch. This silicone-based patch is applied once a day and administrates rotigotine transdermally to the body.

Results demonstrated that rotigotine significantly reduced symptoms of Parkinson's disease. The observed treatment effect over placebo was statistically significant and clinically relevant. Stable plasma levels were demonstrated during the treatment period with once-daily administration of rotigotine. Rotigotine treatment was well tolerated.

"This study demonstrates that rotigotine can successfully improve the disease symptoms," says Doctor Ray Watts, Professor & Chairman Department of Neurology, University of Alabama (Birmingham), USA and signatory investigator of the phase III trial. "This drug in development provides a strong clinical benefit and the transdermal approach may offer a needed alternative for Parkinson's disease patients unable to take oral medications."

"In three consecutive trials rotigotine treatment resulted in a clinically relevant superiority over placebo", Professor Iris Loew-Friedrich, MD, PhD, Member of the Executive Board of SCHWARZ PHARMA, says. "After a 24-week maintenance period, rotigotine has shown a significant reduction in symptoms whereas the disease signs increased with placebo. With more than 95% of the completers from

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June 23, 2004

Page 2 of 2

the Phase III trial continued into an open-label extension trial, rotigotine appears to offer patients a well-accepted treatment option. We are looking forward to submitting applications for market approval for the Parkinson Patch in the third quarter 2004."

In this multi-center double-blind, dose-escalation trial 277 patients with early-stage, idiopathic Parkinson's disease (Hoehn & Yahr stage =3) had been randomized. Patients were titrated up to 7.2 mg/24h with a maintenance period of 6 months. The maximum treatment exposure was 7 months.

The primary variable was the average reduction of symptoms by rotigotine compared to baseline (placebo). This was measured by the UPDRS and the responder rate. UPDRS, the Unified Parkinson's Disease Rating Scale, is a standardized measure of patients' abilities to perform basic motor skills, as well as activities of daily living and mental abilities.

Rotigotine resulted in a significant improvement in the absolute UPDRS (Parts II and III) subtotal score at the end of the treatment (approximately 5.3 points difference from placebo,  $p < 0.0001$ ). The proportion of responders was significantly higher at the end of the treatment compared with placebo (48% vs. 19%,  $p < 0.0001$ ). The most frequent adverse events during the maintenance phase were (Rotigotine/Placebo): Application site reaction (29/7%), somnolence (14/8%), dizziness (11/11%), fall (11/10%), nausea (10/7%), headache (7/3%) and vomiting (5/0%). Adverse events due to hallucination, confusion, and hypotension either did not occur or occurred at rates similar to placebo.

SCHWARZ PHARMA AG (headquartered in Monheim, Germany) develops and markets innovative drugs for unmet medical needs with focus on neurology, urology and cardiovascular diseases. In 2003 the company achieved global sales of € 1,496 million, thereof 85% on international markets outside Germany. 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](http://www.schwarzpharma.com)  
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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.