



News Release

New antihypertensive PritorPlus® 80/25 and Kinzalkomb® 80/25 approved by EU Commission

Leverkusen, April 17, 2008 – Bayer Schering Pharma was granted European marketing authorization for its new antihypertensive fixed dose combination drug PritorPlus® 80/25 and Kinzalkomb® 80/25 (80 mg telmisartan/25 mg hydrochlorothiazide) by the European Commission. The new formulation will be launched in Germany later this month, to be followed soon by selected countries in the EU.

The product is indicated for the treatment of essential hypertension in patients whose blood pressure is not adequately controlled on PritorPlus® 80/12.5 and Kinzalkomb® 80/12.5 (80 mg telmisartan/12.5 mg hydrochlorothiazide), or patients who have been previously stabilized on telmisartan and hydrochlorothiazide separately at the same dosages.^{1,2}

“For physicians and patients, it is often very challenging to reach the recommended blood pressure targets with the available treatments. PritorPlus® 80/25 and Kinzalkomb® 80/25 offer physicians a new therapeutical strategy to treat their hypertensive patients”, said Dr. Rahul Agrawal, Global Clinical Leader Cardiology, Bayer HealthCare.

European approval of PritorPlus® 80/25 and Kinzalkomb® 80/25 follows the submission of efficacy and safety data from 12 clinical trials performed in patients with mild to moderate hypertension. The core clinical development program consisted of two consecutive trials. The superiority of the fixed dose combination, 80 mg telmisartan/25 mg hydrochlorothiazide (T80/H25), versus 80 mg telmisartan/12.5 mg hydrochlorothiazide (T80/H12.5) was demonstrate.¹

971 patients¹, who were inadequately controlled for their blood pressure (BP) on existing antihypertensive treatment, were enrolled in the program. Treatment with T80/H25 provided superior trough systolic and diastolic blood pressure lowering power* after 8 weeks treatment¹ compared to T80/H12.5. In the consecutive follow-up trial, 639 patients (633 patients evaluated for efficacy) were treated with the T80/H25 for a further 6 months. At the end of this treatment interval, the proportion of patients achieving DBP control had increased from 52.4% to 71.4%.² No clinically meaningful differences in the adverse event profiles of T80/H25 and T80/H12.5 were detected. No specific increased incidence was identified for all adverse events. No additional specific safety issues have been identified.^{1,2}

Other studies considered by the EMEA showed that T80/H25-based treatment led to a significant greater lowered trough systolic and diastolic blood pressure than treatment with 160 mg valsartan /25 mg hydrochlorothiazide, the market-leading ARB's high-strength combination.³

About Telmisartan

Telmisartan was discovered and developed by Boehringer Ingelheim. The company markets telmisartan in 84 countries around the world, including the United States, Japan and European countries, under the trademarks Micardis[®] and MicardisPlus[®] (in combination with HCTZ). Bayer Schering Pharma promotes telmisartan under the brand names Pritor[®], PritorPlus[®] (in combination with HCTZ) and Kinzalmono[®], Kinzalkomb[®] (in combination with HCTZ) in markets across Europe.
www.pritor.com / www.kinzal.com / www.icmaedu.com

About Bayer HealthCare

Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma and as Bayer HealthCare Pharmaceuticals in the US and Canada. Bayer HealthCare's aim is to discover and

* -1.6 mmHg, 95% CI from -2.5 to -0.6 mmHg (p=0.0012)) and -2.7 mmHg, 95% CI from -4.2 to -1.2 mmHg (p=0.0003) respectively

manufacture products that will improve human and animal health.
worldwide.www.bayerhealthcare.com

About Bayer Schering Pharma

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, Hematology/Cardiology, Oncology, Primary Care, Specialized Therapeutics and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life. www.bayerscheringpharma.de

Contact

Yvonne Möller Tel.: +49 (0) 30 468 17 389, fax: +49 (0) 30 468 16 710
E-mail: yvonne.moeller@bayerhealthcare.com

ym (2008-172e)

Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them/b to future events or developments.

References

¹ *Trials.Boehringer-Ingelheim.com. Boehringer Ingelheim Trial Number 502.480*

² *Trials.Boehringer-Ingelheim.com. Boehringer Ingelheim Trial Number 502.491*

³ *White WB, Murwin D, Chrysant SG, Koval SE, Davidai G, Guthrie R. Blood Press Monit. 2008 Feb;13(1):21-27*