



## News Release

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20<sup>th</sup> European Society of Hypertension (ESH) Congress:

### **TALENT Study Shows: Starting with a Combination of Adalat<sup>®</sup> GITS and Pritor<sup>®</sup>/Kinzal<sup>®</sup> Achieves Early Blood Pressure Control than Initiating Monotherapy with Either Combination Component**

- First study ever to examine blood pressure-lowering efficacy of the combination of nifedipine (Adalat<sup>®</sup> GITS) with telmisartan (Pritor<sup>®</sup>/Kinzal<sup>®</sup>)

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**Oslo, Norway / Berlin, Germany, June 19, 2010** – Bayer Schering Pharma AG presented today initial findings from **TALENT** (a multicenter sTudy evALuating Efficacy of Nifedipine GITS – Telmisartan Combination in blood pressure control and beyond: Comparison of two strategies) at the 20<sup>th</sup> European Society of Hypertension (ESH) Congress in Oslo, Norway. TALENT is the first trial to examine this specific drug combination for managing blood pressure (BP) in poorly controlled hypertensive patients with additional cardiovascular (CV) risk factors. The primary goal when treating hypertension is to achieve BP control quickly. TALENT shows that initiating antihypertensive therapy with the combination of the calcium channel blocker (CCB) Adalat<sup>®</sup> GITS (GastroIntestinal Therapeutic System) and the angiotensin receptor blocker (ARB) telmisartan (Pritor<sup>®</sup>/Kinzal<sup>®</sup>), leads to earlier BP reduction and control, in high CV risk patients, compared with any monotherapy.

“These initial results from the TALENT trial reinforce the clinical practice debate that to achieve early BP control in high-risk hypertensive patients, it is more beneficial to start with combination antihypertensive therapy, than to start with monotherapy and then add another drug”, said a principal investigator of TALENT, Professor Giuseppe Mancia, Head of the Division and Department of Internal Medicine at San Gerardo Hospital Monza, and Chairman of the Department of Clinical Medicine and Prevention at the University of Milano-Bicocca, Italy. “The early blood pressure reduction was shown for both office and ambulatory BP.”

TALENT, a 16-week multicenter, prospective, randomized, double-blind trial, recruited 405 high CV risk patients, from 40 centers in Italy and Spain. The patient population

was divided into three treatment arms: combination therapy with nifedipine GITS (20mg) and telmisartan (80mg), or initiating with monotherapy of nifedipine GITS 20mg or telmisartan 80mg, then adding the second drug, telmisartan 80mg or nifedipine GITS 20mg, respectively. The primary endpoint of TALENT, to assess 24-hour mean systolic BP (SBP) by ambulatory blood pressure monitoring (ABPM) after 16 weeks compared with baseline, was met.

Already after 8 weeks of treatment, the combination of nifedipine GITS and telmisartan reduced office BP from a baseline of 153/90mmHg to 138/83mmHg, however a BP-lowering effect was evident as early as two weeks. With 24-hour ABPM, BP was reduced from 136/80mmHg at baseline to 126/76mmHg at week 8. The reduction in BP was sustained at week 24.

“Achieving BP goals in high CV risk patients, such as those recruited in TALENT, is a challenge in clinical practice today”, said Professor Luis Ruilope, Associate Professor of Internal Medicine at the Complutense University, Head of the Hypertension Unit at Octubre Hospital, in Madrid, Spain, and second principal investigator of the TALENT trial. “In the upcoming data evaluation of the study we will look for a number of efficacy parameters based on ABPM data, among them the smoothness index. This can determine how homogeneous the BP fall induced by treatment is over 24 hours, with consequences for the protection of the organs exposed to the damage induced by a BP elevation.”

The primary goal when treating hypertension is to achieve BP control quickly. The ESH/ESC Guidelines 2007 and the ESH/ESC Guidelines Reappraisals 2009 recognize the importance to reach BP control quickly and recommend the use of combination antihypertensive therapy to achieve BP goals.<sup>1,2</sup> The combination of a CCB with a renin-angiotensin-aldosterone system (RAAS) blocker, such as an ARB, is recommended by the European guidelines as a rational and effective approach. Calcium channel blocker's are an ideal antihypertensive treatment partner with ARBs, synergistically providing optimal BP control, with the potential for minimizing side-effects.<sup>3</sup> A combination of nifedipine GITS and an ARB provides smooth 24-hour BP control, which is important for reducing target organ damage and CV morbidity.<sup>4,5</sup>

“We are delighted to be announcing initial findings from the much anticipated TALENT trial. The data presented today are exciting as well as encouraging as they underline the continued importance of our products Adalat GITS and Pritor/Kinzal in the

management of hypertension”, said Dr Flemming Oernskov, Head of Bayer Schering Pharma’s Global Business Unit Women’s HealthCare & General Medicine.

### **About TALENT**

TALENT was a 16-week multicenter, prospective, randomized, (double-blind), parallel group (three arms) trial which recruited 405 patients, from 40 centers in Italy and Spain. Patient inclusion criteria included an office SBP of  $\geq 135$ mmHg and at high CV risk due to underlying diabetes, metabolic syndrome and/or organ damage. Patients were randomized to receive one of two treatment strategies, either initiating with combination therapy of nifedipine GITS (20mg) plus telmisartan (80mg), or a more ‘stepped-care’ approach of initiating with one of the drugs then adding the second after 8 weeks. Office and ambulatory BP were measured after 2, 8, 16 and 24 and after 8, 16 and 24 weeks of treatment, respectively. The primary study endpoint was to assess 24-hour mean systolic BP by ABPM at 16 weeks. Secondary endpoints included the assessment of office BP, morning BP surge, night-time average BP, and BP variability. Metabolic parameters, such as fasting blood glucose and total cholesterol, microalbuminuria, and inflammatory markers such as C-reactive protein were also assessed. These data are currently assessed and will be presented at a later time.

### **About Adalat<sup>®</sup> (nifedipine) GITS**

Adalat GITS is a well-established CCB that has been widely used as an antihypertensive and anti-anginal agent for many years. The unique GITS formulation consists of a drug reservoir surrounded by a semi-permeable membrane, which has a single precision-laser-drilled pore on the drug-reservoir side. The Adalat GITS formulation delivers a constant plasma level of nifedipine over 24 hours, avoiding unwanted side effects that may be seen with shorter-acting agents. The clinical efficacy of Adalat, including in patients with increased CV risk, has been demonstrated in a number of important clinical trials. A Coronary Disease Trial Investigating Outcome with Nifedipine GITS (ACTION)<sup>6</sup> extends the evidence base for Adalat established by the International Nifedipine GITS study: Intervention as a Goal in Hypertension Treatment (INSIGHT)<sup>7</sup> and the Evaluation of Nifedipine and Cerivastatin on Recovery of Coronary Endothelial Function (ENCORE) trials.<sup>8,9</sup> In addition to its BP-lowering effect, these studies confirmed that Adalat GITS has vascular-protective properties that help further reduce CV risk, which translates into improved clinical outcomes. Recent research suggests that the results of studies like INSIGHT and ACTION can only be applied to Adalat GITS – generic long-acting formulations of nifedipine have different pharmacokinetic and pharmacodynamic properties.<sup>10,11</sup>

### **About Pritor<sup>®</sup>/Kinzal<sup>®</sup> (telmisartan)**

Bayer HealthCare/Bayer Schering Pharma promotes telmisartan under the brand names Pritor<sup>®</sup>, PritorPlus<sup>®</sup> (in combination with HCTZ) and Kinzalmono<sup>®</sup>, Kinzalkomb<sup>®</sup> (in combination with HCTZ) in markets across Europe. The efficacy and tolerability of telmisartan has previously been demonstrated in the Ongoing Telmisartan Alone and in combination with Ramipril Global Endpoint Trial (ONTARGET) program, which has been the largest ARB trial undertaken to date. ONTARGET confirmed that the ARB telmisartan was as effective as ramipril (an angiotensin converting enzyme inhibitor), the current gold standard for the reduction of CV risk reduction. In addition, the trial also demonstrated telmisartan to be better tolerated by patients, compared with ramipril.<sup>12</sup> 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<sup>®</sup> and MicardisPlus<sup>®</sup> (in combination with HCTZ).

### **About Bayer HealthCare**

The Bayer Group is a global enterprise with core competencies in the fields of healthcare, nutrition and high-tech materials. 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, Medical Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma. Bayer HealthCare's aim is to discover, manufacture and market products that will improve human and animal health worldwide. Find more information at [www.bayerhealthcare.com](http://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, General Medicine, Specialty Medicine 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. Find more information at [www.bayerscheringpharma.de](http://www.bayerscheringpharma.de).

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### **Forward-looking statements**

This news 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](http://www.bayer.com). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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