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SPP100 (TEKTURNA/RASILEZ) DEMONSTRATES POTENTIAL TO PROTECT KIDNEYS FROM DAMAGE

Potential kidney-protective benefits of SPP100 independent of proven blood pressure reduction

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Data from the AVOID study published in this week's New England Journal of Medicine demonstrate that the first-in-class direct renin inhibitor Rasilez^{®1} (aliskiren), known as Tekturna^{®1} in the US, may have potential kidney-protective benefits that are independent of its already proven ability to provide powerful blood pressure reductions^{2,4}. AVOID is the first substantial clinical trial to present data on potential kidney-protective benefits of Rasilez¹. Damage to the kidneys caused by diabetes is the leading cause of end-stage renal disease in developed countries, affecting more than 1.5 million people worldwide^{2,5}.

In the AVOID study, Rasilez/Tekturna¹ reduced albuminuria, a key indicator of kidney disease, by an additional 20% in type 2 diabetic patients with kidney disease who also had a diagnosis of high blood pressure. These patients were already taking the maximum dose of the angiotensin-receptor blocker (ARB) losartan, which has been shown to slow the progression of diabetic kidney disease^{2,6}.

In patients with diabetes, the first sign of kidney disease is the presence of albumin in the urine, a condition called albuminuria³. Albuminuria is a key indicator of kidney disease and cardiovascular disease³. Reducing albuminuria is associated with a reduction of cardiovascular events⁷ and slows the progression of kidney disease, which can reduce the risk of chronic kidney failure in type 2 diabetic patients with kidney disease and high blood pressure^{8,9}.

Dr. Thomas Littke, Head of Clinical Research & Development commented: "Type 2 diabetic patients with high blood pressure are very fragile patients. Importantly, SPP100 further lowered albuminuria by 20% in these patients, independent of blood pressure, when administered on top of losartan (ARB), a standard therapy used to treat diabetic kidney disease. Albuminuria is an important indicator of kidney disease and the level of albuminuria predicts cardiovascular mortality in patients with diabetes".

Dr. Alice Huxley, CEO stated: "We are delighted that the published data in the prestigious New England Journal of Medicine show the potential of SPP100 (Rasilez/Tekturna¹) in kidney protection. This is very important for the future positioning of renin inhibition in medical practice. Speedel's next generation renin inhibitors are specifically designed to enhance the effects of lowering of albuminuria to aid in kidney protection."

Media Release

AVOID study results

In the 24-week AVOID study involving nearly 600 patients, Rasilez/Tekturna¹ was added to the treatment regimen of type 2 diabetic patients diagnosed with high blood pressure who were already receiving losartan and had albuminuria levels greater than 200 mg/g². The study showed that overall Rasilez/Tekturna¹ (150 mg increasing to 300 mg daily) reduced albuminuria by an additional 20% when added to the maximum dose of losartan (100 mg)². Furthermore, a quarter of patients taking Rasilez/Tekturna added to losartan experienced albuminuria reductions greater than 50% compared to those patients taking losartan alone².

Data from AVOID further showed that Rasilez/Tekturna¹ added to the maximum dose of losartan had similar rates of adverse events as the placebo plus losartan group². Hyperkalemia (elevated potassium levels) was reported as an adverse event in 5.0% of patients taking Rasilez/Tekturna¹ in addition to losartan, compared to 5.7% of those taking placebo plus losartan². Hyperkalemia as a laboratory abnormality was reported in 13.7% of patients taking Rasilez/Tekturna¹ in addition to losartan compared to 10.8% of the patients taking placebo plus losartan².

The AVOID study is one in a series of trials in the landmark ASPIRE HIGHER clinical trial program, the largest ongoing cardio-renal outcomes program, which involves more than 35,000 patients in 14 trials including three new mega-trials. The ASPIRE HIGHER program is studying the effect of direct renin inhibition in a variety of conditions, including diabetic kidney disease and heart failure^{2,10}.

About SPP100 (aliskiren, Tekturna/Rasilez¹)

SPP100 (aliskiren, Tekturna/Rasilez¹) is the first-in-class oral direct renin inhibitor. The development of SPP100 is the result of over 20 years of research on renin. Renin is the rate-limiting enzyme at the top of the Renin Angiotensin System (RAS), a process leading to high blood pressure and organ damage. The RAS is a cascade, starting with renin, leading to angiotensin I and finally to angiotensin II. Angiotensin-converting enzyme inhibitors (ACE-Is) and angiotensin II receptor antagonists (ARBs) have been developed to block this system "down stream" and have shown clinical efficacy in patients with hypertension and other cardiovascular diseases.

By inhibiting renin at the top of the RAS, SPP100 decreases the system's activity, as measured by plasma renin activity (PRA). Lowering PRA is believed to be very important in end-organ protection (e.g. heart and kidney). PRA is an independent risk factor and direct surrogate marker for several cardio-renal diseases, such as myocardial infarction and chronic renal disease. Direct renin inhibitors lower PRA whereas most current leading anti-hypertensive drug classes such as ACE-Is and ARBs increase PRA levels.

Speedel in-licensed SPP100 from Novartis in 1999 and successfully completed 18 clinical trials, through Phase I and II in about 500 patients and healthy volunteers. Based on the results generated during this programme, Novartis exercised a license-back option in 2002, and subsequently Novartis started trials with SPP100 in Phase III as monotherapy for hypertension and in Phase IIb as combination therapy. Regulatory approval was given by the US FDA in March 2007 and by the EU in August 2007. A first fixed-dose combination of SPP100 and the diuretic HCT was approved in the US in January 2008.

Speedel believes that it is the first company to establish successfully a clinical proof of concept in Phase II and to have developed and filed for patent protection a commercially viable manufacturing process for a renin inhibitor, an area of industry research for over 20 years. In a Phase II study of 200 patients conducted by Speedel, it was demonstrated that SPP100 achieves dose-dependent blood pressure reduction. The study also showed that 150mg and 300mg SPP100 once daily were comparable to Losartan 100mg, which is double the usual starting dose of this ARB¹¹.

About Speedel

Speedel is a public biopharmaceutical company that seeks to create value for patients, partners and investors by developing innovative therapies for cardiovascular and metabolic diseases. Speedel is a world leader in renin inhibition, a promising new approach with significant potential for treating cardiovascular diseases. Our lead compound SPP100, Aliskiren (Tekturna/Rasilez¹) the first-in-class direct renin inhibitor, was in-licensed from Novartis in 1999 and licensed-back to Novartis Pharma in 2002 for further development and commercialisation; SPP100 was approved by the FDA in the US in March 2007, and by the EMEA in the EU in August 2007. Our pipeline covers four different modes of action, and in addition to SPP100, includes SPP301 (an endothelin A receptor antagonist) in Phase II, SPP200 (a direct thrombin inhibitor) in Phase II, the next generation renin inhibitors SPP635 (in Phase II), SPP1148 and SPP676 (both in Phase I) and several pre-clinical projects, including SPP2000 (aldosterone synthase inhibitor).

Speedel develops novel product candidates through focused innovation and smart drug development from lead identification to the end of Phase II. We either partner with big pharma for Phase III and commercialisation in primary-care indications, or we may ourselves complete Phase III development in specialist indications. Candidate compounds for development and the company's intellectual property come from our late-stage research unit Speedel Experimenta and from in-licensing. Our team of approximately 80 employees, including over 30 experienced pharmaceutical scientists, is located at our headquarters and laboratories in Basel, Switzerland and at offices in New Jersey, USA and Tokyo, Japan.

Speedel was founded in 1998 as a private company. In September 2005 the company's shares were listed on the SWX Swiss Exchange under the symbol SPPN. Further information is available at www.speedel.com.

Forward looking statements

This press release includes forward-looking statements that involve substantial risks and uncertainties. These forward-looking statements are based on our current expectations and projections about future events. All statements, other than statements of historical facts, regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The word "may" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations described in these forward-looking statements and you should not place undue reliance on them. There can be no assurance that actual results of our research and development activities and our results of operations will not differ materially from these expectations. Factors that could cause actual results to differ from expectations include, among others: our or our partners' ability to develop safe and efficacious products; our or our partners' ability to achieve positive results in clinical trials; our or our partners' ability to obtain marketing approval and market acceptance for our product candidates; our ability to enter into future collaboration and licensing agreements; the impact of competition and technological change; existing and future regulations affecting our business; changes in governmental oversight of pharmaceutical product development; the future scope of our patent coverage or that of third parties; the effects of any future litigation; general economic and business conditions, both internationally and within our industry, including exchange rate variations; and our future financing plans.

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¹ Tekturna/Rasilez® are Novartis trademarks.

² Parving H-H et al. Aliskiren Combined with Losartan in Type 2 Diabetes and Nephropathy. *New England Journal of Medicine*.

³ National Institute of Diabetes and Digestive and Kidney Diseases. National Kidney and Urologic Diseases Information Clearing House; NIH Publication No. 06-4732. September 2006; www.kidney.niddk.nih.gov

⁴ Tekturna® (aliskiren) Prescribing Information. Available at: www.tekturna.com. Accessed 5 May 2008.

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⁸ de Zeeuw D, Remuzzi G, Parving H-H, et al. Proteinuria, a target for renoprotection in patients with type 2 diabetic nephropathy: Lessons from RENAAL. *Kidney International* 2004; 65:2309-2320.

⁹ Ibsen H, Olsen MH, Wachtell K, et al. Reduction in albuminuria translates to reduction in cardiovascular events in hypertensive patients: losartan intervention for endpoint reduction in hypertension study. *Hypertension* 2005;45:198-202.

¹⁰ Pitt B, McMurray J, Latini R, et al. Abstract 2491: Neurohumoral Effects Of A New Oral Direct Renin Inhibitor In Stable Heart Failure: The Aliskiren Observation Of Heart Failure Treatment Study (ALOFT). *Circulation*.2007;116:II_549

¹¹ Stanton, Jensen, Nussberger, O'Brien, *Hypertension*.2003; 42: 1137-1143