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New pre-clinical and clinical data for SPP635 and SPP301

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Speedel Holding Ltd. (SWX: SPPN) today announced that data for two of its developmental product candidates were presented at Hypertension 2008, the joint meeting of the International Society of Hypertension (ISH) and the European Society of Hypertension (ESH) in Berlin (14-19 June 2008). Results from the Phase IIa proof-of-concept trial with SPP635, one of the company's next generation of renin inhibitors, demonstrated strong efficacy and good safety^{2,3}. Based on these results Speedel continues Phase IIa development in a special population of diabetic patients with mild-to-moderate hypertension. For SPP301, an endothelin receptor A antagonist in development for patients with diabetes, results of several pre-clinical investigations were presented^{4,5,6}.

Klaus Dembowsky, M.D. Ph.D., Managing Director Speedel Experimenta stated: "The pre-clinical and clinical contributions of Speedel to this important meeting on hypertension and related diseases underline the scientific orientation of our company. Speedel is focused on cardiovascular and metabolic diseases targeting innovations that will ultimately lead to improved treatment options for physicians and benefits for their patients."

Pre-clinical and clinical data on SPP635

The clinical study presented at Hypertension 2008 investigated the safety and efficacy of SPP635 in a double-blind, placebo-controlled, randomised, parallel design². Twenty patients with mild-to-moderate hypertension received a single daily dose of SPP635 while 15 patients received placebo for 4 weeks. Sitting blood pressure as well as 24-hour ambulatory blood pressure (ABP) were the main criteria of efficacy.

Compared to placebo, SPP635 was more efficacious in lowering blood pressure, both systolic and diastolic, during day-time and night-time - and over 24 hours, as assessed by ABP. Sitting blood pressure data were comparable to ABP. These data confirm the potential use of SPP635 as a once-daily drug. SPP635 was safe and well tolerated over the 4 week treatment period. There were neither any serious adverse events reported nor were there any clinically significant changes in laboratory safety parameters.

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Treatment with SPP635 decreased ABP (mean \pm SEM) compared to placebo (24-hour systolic ABP -12.5 ± 1.70 mmHg vs. $+1.5 \pm 1.59$ mmHg, diastolic ABP -8.4 ± 1.09 mmHg vs. -0.1 ± 1.10 mmHg). Moreover, there was a significant decrease in ABP not only during the daytime (systolic BP effects of SPP635 vs. placebo: -14.4 ± 2.01 mmHg vs. $+0.9 \pm 2.17$ mmHg; diastolic BP lowering of SPP 635 vs. placebo: -9.6 ± 1.38 mmHg vs. -0.7 ± 1.55 mmHg) but also during night-time (systolic BP effects of SPP635 vs. placebo: -9.7 ± 1.80 mmHg vs. $+2.7 \pm 2.17$ mmHg; diastolic BP lowering of SPP 635 vs. placebo: -6.9 ± 1.20 mmHg vs. $+2.4 \pm 2.26$ mmHg), indicating a persistent 24-h ABP reduction through a long-term effect of the renin inhibitor. Similar results were observed for sitting blood pressure. The effects on ABP were associated with a significant decrease in the plasma renin activity in the SPP635 treatment group.

In a pre-clinical study, pharmacokinetic and pharmacodynamic properties of SPP635 were investigated³. The data demonstrate that SPP635 has very favourable properties including long half-life in rats and dogs (3.6 h and 8 h, respectively), high oral bioavailability (87% and 50%, respectively), good efficacy in lowering blood pressure and preventing renal damage in animal models. These properties predispose SPP635 for clinical development in hypertension and end organ protection, e.g. a condition such as diabetic kidney disease.

SPP635 belongs to the next generation of renin inhibitors following Speedel's lead compound SPP100 (aliskiren; Rasilez/Tekturna¹), which is partnered with Novartis and has obtained marketing authorisations in USA, the European Union and many other countries. SPP635 is the most advanced compound in the SPP600 series and is one of several new proprietary renin inhibitors invented by Speedel Experimenta, the company's late-stage research unit. Clinical profiling of SPP635 is ongoing in special populations (diabetic patients with mild-to-moderate hypertension). The trial is being carried out in Europe with results due in the second half of 2008.

Pre-clinical data on SPP301

A study in rats demonstrated for the first time that the endothelin receptor A antagonist SPP301 (avosentan) may cause leakage of fluid from the intravascular into the extravascular space⁵. Fluid leakage was assessed as changes in hematocrit. Fluid shift may be one of the causes of fluid retention and oedema observed in the ASCEND study in patients with diabetic nephropathy when treated with SPP301. Most importantly, this animal study provides clear evidence that the fluid shift is concentration dependent and only occurs with the highest concentrations. These data provide the rationale for a new clinical Phase II study in patients with diabetic nephropathy with lower doses of SPP301 thus avoiding fluid retention and oedema.

The results of a further study with SPP301 (avosentan) in a mouse model of diabetic kidney disease demonstrate a strong anti-albuminuric efficacy of this compound⁶. Albuminuria (presence of albumine in the urine) was markedly reduced in diabetic mice after treatment for 20 weeks. This effect was dose-dependent and was accompanied by an improvement in parameters of renal structural damage, a decrease in collagen, and profibrotic gene expression in the kidney. At the highest dose, all changes were highly significant ($p < 0.05$). In addition, there was a trend for the highest dose of SPP301 to be more effective than an angiotensin converting enzyme (ACE) inhibitor (quinapril). These data demonstrate for the first time that the marked reduction of albuminuria in patients treated with SPP301 may be due to a profound reduction of fibrotic parameters underlying the renal injury in diabetic kidney disease.

A study in transgenic rats (expressing human renin and angiotensinogen) with a strongly activated renin angiotensin system investigated the effects of the angiotensin receptor blocker (ARB) valsartan and SPP301 (avosentan) on hypertensive renal damage⁴. This model is characterized by strong hypertension, renal failure with albuminuria and high mortality. Both drugs given orally alone reduced mortality, albuminuria and histological kidney damage demonstrating that both angiotensin II and

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endothelin play an important role in the renal damage in this animal model. The effect on albuminuria was already present after a shorter period of treatment. When both drugs were given in combination there was a marked additive effect on albuminuria and kidney damage as well as mortality. These findings suggest that angiotensin II and endothelin may act through separate pathways and support the hypothesis of additive effects of both treatments in patients with diabetic kidney disease.

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 (Rasilez/Tekturna¹) 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 receptor A 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 SPP2475 (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 Rasilez/Tekturna[®] are Novartis trademarks.

² Hengelage T, Herold P, Jensen C, Baltatu OC. Efficacy and safety of the oral renin inhibitor SPP635 once daily in patients with mild to moderate hypertension.

³ Zaugg CE, Louie P, Dembowsky K, Jensen C, Baltatu OC. Preclinical pharmacokinetic and pharmacodynamic characterization of SPP635, a new direct renin inhibitor.

⁴ Baltatu OC, Zaugg CE, Bader M, Dembowsky K. Additive kidney protective effects of an angiotensin receptor antagonist combined with the endothelin type A receptor antagonist SPP301 in a rat model of malignant hypertension.

⁵ Maillard MP, Wang Q, Baltatu OC, Burnier M. Do endothelin receptor antagonists induce edema through an extravasation of fluids? Evidence from an experiment in bi-nephrectomized rats.

⁶ Jandeleit-Dahm K, Watson A, SoroPaavonen A, Allen T, Thomas M, Schumacher C, Cooper M. The novel endothelin receptor A (eT-A) antagonist SPP 301 attenuates albuminuria and renal structural injury in streptozotocin- induced diabetic apoE knockout mice.