

## Media Release

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### **SPEEDEL REPORTS SUCCESSFUL SPP635 PHASE IIA TRIAL IN HYPERTENSION - Next generation renin inhibitor to continue Phase II profiling in diabetic patients -**

**Basel/Switzerland and Bridgewater NJ/USA, 28 June 2007**

Speedel (SWX: SPPN) today announced that it has reached another significant milestone in the development of its family of renin inhibitors with the successful completion of a Phase IIa proof-of-concept clinical trial with SPP635 for the treatment of hypertension. Based on these positive results, the company is to continue developing SPP635 in Phase II in a special population of diabetic patients with mild-to-moderate hypertension. This compound is the first of a next generation of renin inhibitors following Speedel's lead product SPP100 (aliskiren, Tekturna/Rasilez<sup>1</sup>), which is partnered with Novartis and recently obtained US marketing approval from the FDA and a positive opinion from the CHMP in Europe<sup>2</sup>. 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.

#### **Phase IIa results demonstrate strong efficacy and good tolerability**

The trial had a double-blind, placebo-controlled, randomised, parallel design and it evaluated patients treated with a single dosage level of SPP635 once-daily for 4 weeks. It studied the safety and efficacy of SPP635 in 35 male and female patients (20 patients receiving SPP635 and 15 receiving placebo) with mild-to-moderate hypertension by measuring office and ambulatory blood pressure<sup>3</sup>.

SPP635 was safe and well tolerated over the 4 week period. There were no serious adverse events reported nor were there any clinically significant changes in laboratory safety parameters. Sitting systolic blood pressure was significantly reduced by 17.9 mmHg from 156.6±9.1 mmHg at baseline (mean ± SD) to 138.7±13.3 mmHg in the SPP635 treated group after 4 weeks (p<0.001). The placebo group remained unchanged (156.1±9.0 to 153.2±8.9 mmHg; baseline vs. end of treatment). Diastolic blood pressure was also significantly reduced by 9.8 mmHg from 91.3±7.8 to 81.5±8.2 mmHg (p<0.001) in the SPP635 treated group compared to the placebo treatment (95.3±5.1 to 93.3±5.4 mmHg). These blood pressure measurements were taken at trough, 24 hours after the previous medication. Similar results were observed for ambulatory blood pressures, which were reduced both during the day as well as in the night.

<sup>1</sup> Tekturna® and Rasilez® are Novartis trademarks in the USA and Europe, respectively

<sup>2</sup> Food and Drug Administration (FDA) and Committee for Medicinal Products for Human Use (CHMP)

<sup>3</sup> Ambulatory blood pressure is measured by a portable device worn by the patient over 24 hours at pre-determined intervals

Office blood pressure (systolic and diastolic) is measured when the patient is in the physician's office at pre-determined intervals

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The half-life of SPP635 had been previously reported to be approximately 24 hours suggesting once daily administration; these latest ambulatory blood pressure data confirm the use as of SPP635 as an once-a-day drug. The extent of blood pressure reduction is similar to those reported for the renin inhibitor SPP100 (aliskiren, Tekturna/Rasilez)<sup>4</sup>.

**Hans R. Brunner, Professor Emeritus of Medicine at the University of Lausanne, and acting Speedel Medical Director**, commented: “These positive results show that SPP635 has comparable efficacy to other blood pressure lowering therapies. It will be exciting to see the first follow-on renin inhibitor to SPP100 demonstrate its potential in diabetic patients in further clinical trials.”

**Alice Huxley, CEO of Speedel**, commented: “This success with SPP635 reinforces Speedel’s strategy of building a family of renin inhibitors which can be profiled for both general and special patient populations. We continue to leverage our exceptional knowledge in renin inhibition which we believe has the potential to be the next gold standard for the treatment of different cardiovascular diseases.”

### Continued Phase II development

Clinical profiling of SPP635 will continue this year in special populations with a further study planned in diabetic patients with mild-to-moderate hypertension. This harder to manage patient group has been shown to respond to SPP100 to controlling blood pressure alone and in combination with an ACE-I<sup>5</sup>. Further details about this proof-of-concept Phase II trial will be announced later in 2007 when it commences. The trial will be carried out in Europe with results due in the second half of 2008.

Speedel’s next generation renin inhibitors include other compounds in the SPP600 series, the SPP1100 series with SPP1148 due to report first Phase I results in Q42007, and the SPP800 series currently in late-stage pre-clinical profiling. Each series is a different chemical class with distinct properties and is protected by different patent applications.

### About SPP600 series

SPP635 is the most advanced compound of the SPP600 series of renin inhibitors being developed by Speedel. The company has made significant progress in the optimisation and development of this series of newly synthesised compounds by using rational drug design, including computer assisted molecular modelling techniques, state-of-the-art preclinical disease models and human microdosing.

In December 2001, Speedel acquired a worldwide exclusive license from Roche covering its entire programme in renin inhibition. This license allows Speedel to use the acquired know-how for lead optimisation of its own compounds designated as the SPP600 series. Speedel holds full development and commercialization rights for these product candidates under the license agreement with Roche. If Speedel decides to offer rights to any Speedel compound from the series to a third party, Roche has a right of first negotiation with respect to such rights. If Roche has not expressed its interest in acquiring such rights within a defined period of time, or the parties have not reached an agreement on the terms of such rights, Speedel is free to grant such rights to any third party.

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<sup>4</sup> Aliskiren Reduces Blood Pressure and Suppresses Plasma Renin Activity in Combination With a Thiazide Diuretic, an Angiotensin-Converting Enzyme Inhibitor, or an Angiotensin Receptor Blocker O’Brien E; Barton J; Nussberger J; Mulcahy D; Jensen C; Dicker P; Stanton A, Hypertension. 2007;49:276-284.

<sup>5</sup> Angiotensin Converting Enzyme Inhibitor

<sup>6</sup> Uresin Y et al. Aliskiren, a novel renin inhibitor, has greater BP lowering than ramipril and additional BP lowering when combined with ramipril in patients with diabetes and hypertension. European Society of Hypertension. 16th European Meeting on Hypertension. June 12-15, 2006; Madrid, Spain.

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### About Hypertension

Hypertension is a common disorder in which blood pressure is abnormally high, placing undue stress on the heart, blood vessels and other organs such as the kidney and the brain. Blood pressure is determined in two phases as the heart contracts and relaxes. Systolic blood pressure represents the force that blood exerts on the walls of arteries as the heart contracts to pump out blood. Diastolic blood pressure represents the force as the heart relaxes to allow the blood to flow into the heart.

Due to its wide prevalence and impact on cardiovascular health, hypertension is a major cause of disease and death in Europe and North America. More than one in three Europeans and North Americans over the age of 35 suffers from hypertension – but for the vast majority of patients who undergo hypertension treatment, the causes of high blood pressure are unknown. More than 40 % of patients undergoing treatment with current therapies do not reach targeted blood pressure levels, and so there is a considerable unmet medical need.

The latest potential therapeutic agents for hypertension are renin inhibitors. Renin is an enzyme produced in the kidneys in response to reduced renal perfusion. Through a cascade of biological events, renin acts to bring about sodium retention, an increase in blood pressure, and restoration of renal perfusion, which shuts off the signal for renin release. For hypertensive individuals, renin inhibitors are currently being investigated as a therapy that may provide benefits over current therapies to reduce blood pressure, decrease salt retention and may protect end organs such as the kidney, heart and brain.

### 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 (Tekturna/Rasilez i), 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 filed by Novartis with the EMEA in the EU in Q3 2006. Our pipeline covers three different modes of action, and in addition to SPP100, includes SPP301 in Phase III (on hold), SPP200 in Phase II, SPP635 in Phase II, SPP1148 in Phase I and several pre-clinical projects.

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 70 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.

In January 2007 the company raised gross proceeds of CHF 55.5 million (approximately EUR 34.3 million or USD 44.5 million) through a convertible bond issue. In March 2006 the company raised gross proceeds of CHF 83.95 million (approximately EUR 53m or USD 64m) through the public offering of 500,000 treasury shares. Previously, as a private company, we raised gross proceeds of CHF 255 million (approximately EUR 157 million or USD 204 million) from private placements of equity securities and two convertible loans including the conversion premiums. We have had total revenues, principally from milestone payments, of CHF 57.7 million (approximately EUR 37 million or USD 44 million). The company's shares were listed in September 2005 on the SWX Swiss Exchange under the symbol SPPN.

### 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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<sup>i</sup> Tekturna/Rasilez<sup>®</sup> are Novartis trademarks