

# Media Release



For further information please contact

**Nick Miles**

Director Communications & Investor Relations

**Speedel**

Hirschgässlein 11  
CH - 4051 Basel  
Switzerland

T +41 (0) 61 206 40 00

D +41 (0) 61 206 40 14

F +41 (0) 61 206 40 01

M +41 (0) 79 446 25 21

E [nick.miles@speedel.com](mailto:nick.miles@speedel.com)

[www.speedel.com](http://www.speedel.com)

**Frank LaSaracina**

Managing Director

**Speedel Pharmaceuticals Inc**

1661 Route 22 West  
P.O. Box 6532  
Bridgewater, NJ 08807  
United States of America

T +1 732 537 2290

F +1 732 537 2292

M +1 908 338 0501

E [frank.lasaracina@speedel.com](mailto:frank.lasaracina@speedel.com)

[www.speedel.com](http://www.speedel.com)

## **SPEEDEL AND NOVARTIS WIN *THE WALL STREET JOURNAL* GOLD AWARD**

**- 2007 TECHNOLOGY INNOVATION WINNER FOR DISCOVERING AND DEVELOPING ALISKIREN AS MAJOR BREAKTHROUGH FOR TREATMENT OF HYPERTENSION -**

### **Basel/Switzerland and Bridgewater NJ/USA, 24 September 2007**

Speedel (SWX: SPPN) today welcomed the announcement that Speedel and Novartis have won the overall Gold Award in the seventh annual *Wall Street Journal* contest for Technology Innovation. This Gold Award was given to both companies for their work in discovering and developing SPP100 (aliskiren) the first direct renin inhibitor for treating hypertension. The compound received regulatory approval in 2007 in the US, Europe and Switzerland where it is marketed by Novartis under the trade names Tekturna<sup>1</sup> and Rasilez<sup>2</sup> respectively.

The *Wall Street Journal* received over 800 applications for these awards, and then narrowed the field down to about 150 entries which were reviewed by a distinguished panel of judges from business, research, and academic organisations. To qualify, technologies had to constitute a breakthrough from traditional methods, not just an incremental improvement. There was an overall Gold, Silver and Bronze Award across all entries. Awards were all also made for each of the twelve categories reviewed, including the Medical/Biotech sector which Speedel and Novartis also won.

**Dr. Alice Huxley, CEO**, said: "We are delighted to win this prestigious award. The successful collaboration between Speedel and Novartis is a wonderful example of the dynamism and innovation of a small biotech being complemented with the development resources and marketing power of a global pharmaceutical company. For over forty years the medical community has been waiting for a compound to directly inhibit renin as a key protagonist in causing high blood pressure, and finally in 2007 SPP100 (aliskiren) was successfully brought to patients."

SPP100 (aliskiren) was discovered by scientists at Ciba Geigy in the early 1990s and taken through pre-clinical testing. In 1999 Speedel in-licensed the compound from Novartis and developed it through 18 clinical Phase I and Phase II trials in about 500 patients and healthy volunteers. Speedel was the first company to demonstrate in man that a direct renin inhibitor could effectively and safely lower blood pressure. In addition Speedel was the first company to overcome the traditionally high manufacturing costs of producing renin inhibitors by designing, developing and implementing a new synthetic route for the cost-effective production of SPP100 on a commercial scale. As a result of these achievements Novartis exercised a license-back option for the compound in 2002. Novartis has since taken the compound through extensive Phase III clinical

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development in about 8,000 patients and received regulatory approval for the drug in the US and EU as a monotherapy and in co-administration with other anti-hypertensives.

Hypertension is a leading cause of cardiovascular disease, the world's No 1 killer. There is a clear unmet medical need in this therapeutic area with more than 40% of treated patients not achieving control levels for their high blood pressure - even when using existing therapies.

The Lancet published an editorial on 17 August which stated that: "The risk of becoming hypertensive during lifetime exceeds a staggering 90% for a person in a developed country." The editorial also observed that: "The increasingly common combination and interaction of obesity, diabetes, hyperlipidaemia and high blood pressure, if left untreated for too long, leads to cardiovascular disease, stroke, renal failure, dementia, and ultimately death. Worldwide, the estimated number of adults with hypertension was 972 million in 2000; 639 million live in developing countries. By 2025, the total number is expected to increase to 1.56 billion."<sup>3</sup>

Speedel remains at the forefront of research and clinical development of next generation direct renin inhibitors with SPP635 in Phase IIa, SPP1148 in Phase I and others in pre-clinical development. The Wall Street Journal Gold Award for Technology Innovation highlights Speedel's long standing commitment to direct renin inhibition as the potential gold standard therapy for treatment of hypertension and other related disorders.

### **About SPP100 (aliskiren, Tekturna/Rasilez<sup>4</sup>)**

SPP100 (aliskiren, Tekturna/Rasilez) 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), one of the key regulators of blood pressure. 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.

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 ARB (Stanton, Jensen, Nussberger, O'Brien, Hypertension.2003; 42: 1137-1143).

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## 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<sup>5</sup>), 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 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>1</sup> Tekturna/Rasilez<sup>®</sup> are Novartis trademarks

<sup>2</sup> Tekturna/Rasilez<sup>®</sup> are Novartis trademarks

<sup>3</sup> The Lancet: 2007; 370:539

<sup>4</sup> Tekturna/Rasilez<sup>®</sup> are Novartis trademarks

<sup>5</sup> Tekturna/Rasilez<sup>®</sup> are Novartis trademarks