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## Patients with early Parkinson's disease show better symptom control<sup>1</sup> and improvements in daily activities<sup>1</sup> with Stalevo than levodopa/carbidopa

- *New data intended to support regulatory filings in 2008 with goal of expanding Stalevo indication to include treatment of early Parkinson's disease*
- *Stalevo currently used only when levodopa/carbidopa loses therapeutic effect prior to next scheduled dose<sup>2</sup> (referred to as end-of-dose "wearing off")*
- *Approximately 6.5 million people worldwide suffer from Parkinson's disease<sup>3</sup>, a progressive and disabling neurological condition*

Basel, April 15, 2008 – A new study in patients with early Parkinson's disease demonstrates that Stalevo® (levodopa/carbidopa/entacapone) gives better symptom control<sup>1</sup> and greater improvements in activities of daily living<sup>1</sup> than levodopa/carbidopa, the most widely-used current therapy.

The FIRST STEP study, presented today at the American Academy of Neurology Annual Meeting in Chicago, is intended to support regulatory filings in 2008 for the use of Stalevo in patients with early Parkinson's disease (PD) who have not been treated with levodopa.

"It is important to provide effective therapeutic options for patients with early PD, and levodopa/carbidopa has been considered the most effective treatment for motor symptoms," said Robert A. Hauser, MD, Professor of Neurology, Pharmacology and Experimental Therapeutics at the University of South Florida, and principal investigator of the study. "The results of FIRST STEP indicate that Stalevo may provide greater benefits for patients with early Parkinson's disease over and above levodopa/carbidopa therapy."

Stalevo is currently indicated for certain Parkinson's disease patients who experience end-of-dose motor (or movement) fluctuations, known as "wearing off"<sup>2</sup>. This occurs when the dose of levodopa that initially controlled their symptoms is no longer enough to maintain full control until the next dose<sup>4</sup>.

In the FIRST STEP study in patients with early Parkinson's disease, Stalevo showed a statistically significant improvement versus levodopa/carbidopa in the primary endpoint, which was the combined Unified Parkinson's Disease Rating Scale (UPDRS) Part II-activities of daily living (eating, bathing, dressing) and Part III-motor scores (agility, rigidity, tremors) (p=0.045)<sup>1</sup>.

FIRST STEP (Favorability of ImmEDIATE-Release carbidopa/levodopa vs Stalevo; Short-Term comparison in Early Parkinson's) was a double-blind, randomized, parallel group, fixed-dose clinical trial that included 423 patients with early Parkinson's disease in eight countries<sup>1</sup>.

“This study is part of a research initiative to better understand the potential of Stalevo in the treatment of patients with early Parkinson’s disease,” said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. “The results of FIRST STEP demonstrate the potential for Stalevo to provide benefits for an even greater number of patients suffering from this often devastating disease.”

Parkinson’s disease is a chronic, progressive disorder of the nervous system, which causes increasing disability over time<sup>5</sup> and affects approximately 6.5 million people worldwide<sup>3</sup>. The condition is diagnosed by the appearance of movement-related or ‘motor’ symptoms including tremor, muscular rigidity, stooped posture and slowness or difficulty in movement<sup>6</sup>.

Stalevo is an optimized levodopa therapy combining levodopa and carbidopa with the enzyme inhibitor entacapone, which extends the presence of levodopa in the bloodstream. It was approved by the US Food and Drug Administration in June 2003 and by the European Commission in October 2003, and is now approved in 79 countries. Stalevo is developed and manufactured by Orion Corporation, and is marketed by Novartis and Orion in their respective territories.

The most common side effects of Stalevo are unwanted or uncontrollable movements (known as dyskinesia), nausea, diarrhea, excessive muscle movements (known as hyperkinesia), harmless discoloration of urine, sweat and/or saliva; diminished or slow movements (known as hypokinesia), abdominal pain, dizziness, constipation, fatigue, pain, and hallucinations. Some of the more serious side effects may include severe diarrhea, severe dyskinesia, hallucinations, other mental disturbances, orthostatic hypotension (low blood pressure), rhabdomyolysis (a muscle disease), and symptoms resembling neuroleptic malignant syndrome (a condition characterized by fever and muscle stiffness).

#### **Disclaimer**

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as “potential,” “intended,” “will,” “may,” or similar expressions, or by express or implied discussions regarding potential future regulatory filings or approvals of Stalevo or potential future sales of Stalevo. Such forward-looking statements reflect the current views of Novartis regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Stalevo will be approved in any additional markets or for any additional indication in any market or that Stalevo will reach any particular sales levels. In particular, management’s expectations regarding Stalevo could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected additional analysis of clinical data, or unexpected new clinical data; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government, industry, and general public pricing pressures; production delays or business interruption generally; and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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## References

- 1 Hauser RA, Panisset M, Abbruzzese G, et al. Improved symptom control with fixed dose levodopa/carbidopa/entacapone (Stalevo®) versus conventional levodopa/carbidopa as first-line levodopa therapy in early Parkinson's disease patients. From abstract; poster to be presented at 60th annual meeting of American Academy of Neurology, Chicago 12-19 April 2008.
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- 3 Decision Resources DB 9, Mattson Jack Epidemiology Database.
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## Novartis Media Relations

### Beatrix Benz

Novartis Global Media Relations  
+41 61 324 7999 (direct)  
+41 79 618 7748 (mobile)  
[beatrix.benz@novartis.com](mailto:beatrix.benz@novartis.com)

### Julie Morrow

Novartis Pharma Communications  
+ 41 61 324 1135 (direct)  
+ 41 79 596 4636 (mobile)  
[julie.morrow@novartis.com](mailto:julie.morrow@novartis.com)

e-mail: [media.relations@novartis.com](mailto:media.relations@novartis.com)

## Novartis Investor Relations

<b>Ruth Metzler-Arnold</b>	+41 61 324 9980
Katharina Ambuehl	+41 61 324 5316
Pierre-Michel Bringer	+41 61 324 1065
John Gilardi	+41 61 324 3018
Jason Hannon	+41 61 324 2152
Thomas Hungerbuehler	+41 61 324 8425
Isabella Zinck	+41 61 324 7188

### North America Office

Richard Jarvis	+1 212 830 2433
Jill Pozarek	+1 212 830 2445
Edwin Valeriano	+1 212 830 2456

Central phone no: +41 61 324 7944  
Fax no: +41 61 324 8444  
e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

Fax no: +1 212 830 2405  
e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)