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First results of three multicenter open-label clinical trials with Stalevo™ show improved symptomatic benefits and enhanced convenience for patients with Parkinson's disease.

Basel, 1 September 2003 - Results from new clinical studies with Stalevo™ presented today at the 7th Congress of the European Federation of Neurological Societies in Helsinki, Finland confirm clear patient benefits. Data from these first-ever studies in patients with Parkinson's disease (PD) taking Stalevo – the new levodopa combination product containing levodopa, carbidopa and entacapone– show enhanced symptomatic benefits resulting in greater control of PD symptoms, as well as convenience of administration compared to traditional levodopa therapy.

While levodopa therapy remains the cornerstone of PD treatment, its long term utility is limited by the occurrence of motor complications. Stalevo was therefore developed to optimize the pharmacokinetic profile of levodopa and enhance its clinical benefits.

The individual components of Stalevo have a well-established efficacy record supported by numerous clinical trials[1,2,3,4,5,6], which provided the basis for regulatory agency approval of Stalevo[7]. These first-ever clinical studies provide valuable data regarding dosing, tolerability and efficacy of Stalevo.

Commenting on the clinical relevance of the TC-INIT study[8], one of the lead investigators, Professor David Brooks, of the Medical Research Council Clinical Sciences Centre and Imperial College London, UK said: "These interim data show that levodopa treated PD patients may be switched to Stalevo and experience enhanced benefits of their levodopa therapy. In addition, this real-life experience is significant as it demonstrates that the switch can be achieved easily and conveniently".

The TC-INIT study compares the switch from traditional levodopa/dopa decarboxylase inhibitor (DDCI) therapy to either Stalevo or levodopa/DDCI plus entacapone (Comtess/Comtan) tablets taken separately in 200 PD patients experiencing wearing-off symptoms. Interim results of 111 patients show that patients taking

Stalevo experience improved symptom control comparable to levodopa/DDCI plus entacapone taken separately. At the end of week two, a majority of patients saw their condition improve when their levodopa therapy was optimized. When switched to Stalevo, 82% (investigator assessment) and 81% (patient assessment) of patients reported improved symptom control versus 76% (investigator assessment) and 73% (patient assessment) when switched to levodopa/DDCI plus entacapone taken separately.

In addition, treatment with Stalevo as a single tablet was easy to initiate and provided simplicity and convenience of administration for patients.

Interim data from a second study (SELECT-TC) assessing the switch to Stalevo in 160 PD patients currently being treated with levodopa/carbidopa and experiencing wearing-off

symptoms, indicate that the majority of patients can easily be transferred to Stalevo with few, or no levodopa dose adjustments.[9]

"These data show that dose modifications are rarely needed when switching from levodopa treatment to Stalevo and can be accomplished with ease and convenience, and most importantly with the patient's acceptance. There are a number of complicated regimens that currently exist in PD treatment. Many patients often have to take medications for other co-existing conditions. Stalevo clearly has everyday practical benefits for patients and for physicians prescribing the treatment by combining three medicines in one", added Professor David Brooks.

In a third, four-week completed study (SIMCOM) more than two-thirds of the patients preferred taking Stalevo to levodopa/DDCI and entacapone taken separately. Furthermore, the vast majority of patients reported that Stalevo was easier to dose, use, handle and swallow.[10]

In all studies, Stalevo was generally well tolerated. The most common side effects were dopaminergic in nature (e.g. dyskinesia or involuntary movements, nausea). These side effects are mild and moderate in nature, and when they occur, they can usually be managed with dose modifications. Side effects seldom lead to treatment discontinuation. In addition, the components of Stalevo have a well-established safety and tolerability profile supported by numerous clinical trials[1,2,3,4,5,6] and over 300 000 patient years of experience with levodopa/DDCI plus entacapone.[11]

Novartis and Orion Pharma received US Food and Drug Administration (FDA) approval for Stalevo in June 2003 and have recently [26 June 2003] received a positive opinion from the European Committee for Proprietary Medicinal Products (CPMP).

This release contains certain forward-looking statements relating to the Company's business, which can be identified by the use of forward-looking terminology such as "first-ever studies" or similar expressions, or by express or implied discussions regarding potential future sales of Stalevo. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Stalevo to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that the aforementioned clinical trials will result in the commercialization of Stalevo in any market. Any such commercialization can be affected, among other things, uncertainties relating to unexpected regulatory delays, further clinical trial results, the ability to obtain or maintain patent or other proprietary intellectual property protection, government regulation or competition in general, increased government pricing pressures, as well as factors discussed in the Company's Form 20-F filed 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 described herein as anticipated, believed, estimated or expected.

About Orion Pharma

Orion Pharma is a research and development-orientated pharmaceutical division of the Orion Group (HEX:ORIA, ORIB), which is one of the leading companies in the healthcare sector in the Nordic area of Europe. Pharmaceutical R&D at Orion Pharma focuses on three core therapy areas: CNS therapies, cardiology and critical care, and hormonal therapies. Entacapone, a COMT enzyme inhibitor used in the treatment of Parkinson's disease, is one of Orion Pharma's patented molecule discoveries. It is available globally as Comtess® and Comtan®. It is also one of the three active compounds in Orion's novel levodopa treatment, Stalevo, which is already approved in the US and awaiting European marketing approval. For further information please consult http://www.orionpharma.com/.

About Novartis

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of USD 20.9 billion and a net income of USD 4.7 billion. The Group invested approximately USD 2.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78 200 people and operate in over 140 countries around the world. For further information please consult http://www.novartis.com.

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Notes to Editor:

- Parkinson's disease (PD) is a chronic and progressive neurological condition. The overall prevalence of Parkinson's disease in the world is estimated to be 6.3 million. It affects 1 per 100 persons over the age of 60 years and 1 per 50 people over the age of 80 years[12].
- The cornerstone of PD treatment is levodopa. It can provide benefit throughout the whole course of the disease and is the only medication that has been shown to have an effect on quality of life and significantly prolongs life expectancy in PD patients.[13] However, when standard levodopa therapies are used over the long term, patients may begin to experience a wearing-off of its clinical effects, with changes in mobility, mood and sensation, and treatment may need to be adjusted periodically.
- Stalevo is the first new levodopa treatment in many years and combines levodopa, carbidopa and entacapone. Whilst carbidopa reduces the side effects of levodopa, entacapone enhances its benefits, offering smoother and more consistent plasma levels of levodopa. This optimized pharmacokinetic profile translates into significant improvement in the PD patient's ability to perform everyday tasks and alleviates motor complications associated with long-term therapy.
- Randomized, single-dose, four-way crossover studies investigating the pharmacokinetics of Stalevo in healthy subjects showed that Stalevo was bioequivalent to levodopa/carbidopa and entacapone administered separately without requiring dose modification.[7] The studies evaluated the bioequivalence of Stalevo 50mg, 100mg and 150mg with corresponding doses of levodopa/carbidopa and entacapone and served as the basis for approval by regulatory agencies.

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