Nitec Pharma Reports Positive Phase III Results and Filing in EU for LODOTRA™

Night Time Release Prednisone is Superior to Standard Regimen for the Treatment of Morning Symptoms in Rheumatoid Arthritis

Basel, Switzerland - 28 September 2006 – Nitec Pharma AG, a specialist pharmaceutical company focused on the treatment of chronic inflammatory diseases, today announced positive results in a Phase III clinical trial with Lodotra™, a new, modified-release tablet that has been developed to optimize the efficacy of orally administered low-dose prednisone in Rheumatoid Arthritis (RA). Lodotra provides all the benefits of standard immediate release (IR) prednisone but has the additional, clinically important advantage of reduced morning stiffness combined with a convenient dosing regimen and a comparable safety profile.

The diurnal rhythm in RA is characterised by elevated night time levels of inflammatory cytokines such as IL6, which leads to extreme stiffness and pain in the hours immediately after awaking. It has been established that this morning symptoms can be addressed with prednisone administered at 2 AM. However, until now this has been impossible without disturbing sleep. Lodotra is an oral medication that has a unique delivery system that ensures rapid release of the prednisone from the tablet core about 4 hours after ingestion. Administration of Lodotra at night time (10 PM) results in release of prednisone at about 2 AM for a more effective treatment of the morning symptoms of RA.

The trial involved 288 patients in 26 centres in Europe, and was a randomized, double-blind, active-controlled, parallel-group Phase III study. The study compared the efficacy and safety of Lodotra given to patients before sleep the evening before, with standard immediate-release (IR) prednisone (following the current recommended regimen where prednisone is administered in the morning at 8 AM) over a period of 12 weeks. The duration of morning stiffness (the primary clinical endpoint of the study) was significantly reduced in the Lodotra group while under standard IR prednisone no change in morning stiffness was shown. In half the patients a reduction of more than one hour or one third was observed and those patients also showed a reduction in pain of one third. Lodotra was also shown to be well tolerated and just as safe as the standard regimen. Importantly, IL6 levels were shown to be reduced in the Lodotra group but remained constant in the standard prednisone group indicating that this reformulation of prednisone was exerting a specific inhibitory action on what is thought to be a key biological marker of the inflammatory process in RA.

Prof. Frank Buttgereit, Charite Berlin; principal investigator in the study commented:
“These results confirm the hypothesis that the adaption of the timing of oral glucocorticoids to the circadian rhythms in RA could lead to a more effective therapy without increasing the dose of prednisone. The benefit of Lodota results in a clinically relevant reduction of morning stiffness added to all known therapeutic effects of IR prednisone. The new administration mode is also convenient for the patient and was well tolerated."

"The results of the study confirm our expectations of being able to provide a steroid treatment that directly addresses the problems of morning symptoms in rheumatoid arthritis by

administration of prednisone at a physiologically appropriate time" stated Dr. Achim Schäffler, co-founder and Head of R&D at Nitec Pharma. "Lodotra has been shown to address debilitating and painful morning stiffness and should directly improve the lives of people with RA. Our technology can also be applied to other indications such as Polymyalgia Rheumatica (PMR) and asthma, which we plan to address next."

"We are delighted to have such positive results in a Phase III trial and have already submitted a dossier for marketing authorisation in Europe in August. We also plan to seek marketing authorisation for North America and the Far East," commented Jochen Mattis, co-founder and Head of Marketing and Sales at Nitec Pharma, "We will also be seeking marketing partners to realise the commercial value of Lodotra worldwide, in addition to the agreement we already have with Merck KGaA in Germany and Austria."

About Nitec Pharma AG:
Nitec Pharma is a specialist pharmaceutical company focused on the development and commercialization of optimized medicines for the treatment of chronic inflammatory diseases. Headquartered in Basel, Switzerland with a wholly owned subsidiary in Mannheim, Germany, the Company is developing Lodotra™, a night time release formulation of prednisone, to address morning symptoms such as morning stiffness in rheumatoid arthritis. Lodotra has just successfully completed Phase III trials and Nitec will be using the same modified release technology to develop treatments for other indications such as Polymyalgia Rheumatica (PMR), Asthma and other inflammatory diseases. Nitec was originally created in 2004 in a spin out from Merck KGaA of the night time release technology, originally developed at Merck in cooperation with Skyepharma. For further information about Nitec Pharma please visit www.nitecpharma.com

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Notes for Editors:

Phase III Results for Lodotra™
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The relative change in duration of morning stiffness under Lodotra treatment from baseline to the end of the treatment period was statistically significantly higher than under standard IR prednisone (decrease of 22.7% vs 0.4%; $p = 0.0226$, one sided). A difference of 10% between the two treatment groups was already apparent at week two. Under continued treatment, this difference increased and plateaued at about 30% to 40% from week seven onwards.

In half the patients, the duration of morning stiffness was reduced by at least one hour, or one third, and those patients also showed a reduction in pain of one third. Morning stiffness is one of the most distressing symptoms for RA patients and thus the observed reduction between baseline and the final week under Lodotra can be considered a clinically meaningful improvement.

Furthermore, a significant clinical difference between the IR and Lodotra groups was observed: plasma levels of proinflammatory cytokine IL6 decreased in the Lodotra group but remained constant in the standard prednisone group. The change between baseline and the

end of the double-blind trial was statistically significant in the Lodotra group ($p < 0.0001$), but not in the standard prednisone group ($p = 0.2326$). This confirms the proposed pharmacological rationale for adapting the timing of prednisone administration to the circadian rhythm of RA.

Finally, in clinical practice, the minimum effective dose depends on the individual response to prednisone treatment. As Lodotra improves relief of morning symptoms compared to standard prednisone, it should be possible to lower the dose, resulting in a decreased risk of side effects.