



Nitec to present Lodotra™ 12 month treatment data in Rheumatoid Arthritis at the Annual European Congress of Rheumatology (EULAR) in Paris

Basel, Switzerland, 12 June 2008 – Nitec Pharma AG (“Nitec”), a Switzerland-based specialty pharmaceutical company focused on the development and commercialisation of innovative medicines and effective treatment solutions for chronic inflammation and pain-related diseases, will today present 12 month treatment data on Lodotra™ in rheumatoid arthritis (RA) at the Annual European Congress of Rheumatology (EULAR) in Paris.

Patients who completed the 12 week, randomised, double-blind phase of the circadian administration of prednisone in RA study (CAPRA-1) could elect for continued treatment with modified release (MR) prednisone for an additional 9 months. The study was open-label, non-randomized treatment with Lodotra™.

The controlled double-blind phase had demonstrated that Lodotra™ was more effective than immediate release prednisone at reducing morning stiffness¹. Compared to immediate release prednisone, after 3 months the study population showed a significant reduction in the duration of their morning stiffness of the joints of 22.7% versus 0.4% ($p=0.0452$) and a statistically significant reduction in serum levels of the pro-inflammatory cytokine IL-6 after 3 months of treatment with Lodotra™.

Subsequently, 249 patients who had completed the 3 month trial continued with open-label treatment with Lodotra™ for a further 9 months. After 6 months of treatment with Lodotra™ the reduction of morning stiffness amounted to 54% (103 minutes) compared to baseline. This effect was sustained until the end of the 12 month treatment period (mean reduction of 44.9%, 88 minutes). The reduction of IL-6 levels after treatment with Lodotra™ was also sustained throughout the treatment period and was 45% (median) after 12 months. Elevated serum levels of IL-6 during the night are thought to be a contributing factor to the early morning stiffness of RA patients. The study was conducted in collaboration with Prof. Dr. med. Frank Buttgerit from the Charité – Universitätsmedizin Berlin (Department of Rheumatology and Clinical Immunology), Merck KGaA and Nitec and follow-up results were first presented at the annual meeting of the American College of Rheumatology (ACR) in November 2007. The results of the 3 month phase III double-blind controlled trial were published in *The Lancet* in January 2008 (*The Lancet* 2008; 371: 205-214).

Dr Anders Härfstrand, CEO of Nitec: “We are proud to present long-term data on Lodotra™ at the EULAR congress today. Morning stiffness is one of the debilitating symptoms of RA and reducing this by approximately 50% delivers great relief and benefit to RA patients. We look forward to bringing Lodotra™ to the market.”

Nitec is awaiting marketing approval of Lodotra™ in 15 European countries via the decentralized procedure.

¹ Buttgerit et al. Efficacy of modified-release versus standard prednisone to reduce duration of morning stiffness of the joints in rheumatoid arthritis (CAPRA-1): a double-blind, randomized controlled trial. *The Lancet* 2008; 371: 205-214

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About Nitec Pharma AG:

Nitec Pharma is a Switzerland-based specialty pharmaceutical company focused on the development and commercialisation of innovative medicines and effective treatment solutions for chronic inflammation and pain-related diseases. The Company's most advanced product is Lodotra™, a circadian cytokine modulator (CCM) for the treatment of rheumatoid arthritis (RA). Nitec was originally founded in 2004 as a spin-out of Merck KGaA and is headquartered in Reinach, Basel-Landschaft in Switzerland. The Company is financed by Atlas Venture, Global Life Science Ventures and NGN Capital. For further information about Nitec please visit www.nitecpharma.com

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