



8th International Congress on PSYCHOPHARMACOLOGY

& 4th International Symposium on Child and Adolescent Psychopharmacology

*Progress in Psychopharmacology: Advanced Diagnostic
Systems and Neuroscience-Based Nomenclature*

April 20th - 24th 2016, Kervansaray Lara Hotel, Antalya - TURKEY



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SYMPOSIUM NAME: Joint Symposium 10:

European regulator's view on drug development and pivotal trials within psychopharmacology

SYMPOSIUM DATE & TIME: April 23, 09:00-10:30

PRESENTATION TITLE: Current scientific EMA¹/CHMP² clinical guidelines within psychopharmacology; recent updates and highlights

¹EMA (European Medicines Agency)

²CHMP (Committee for Medicinal Products for Human Use)



NAME-SURNAME, TITLE:

Dag Nilsson, specialist in Neurology, M.D., Ph.D.

INSTITUTION AND POSITION:

Medical Products Agency, Sweden, since 2007. CNS Efficacy and Safety Clinical Assessor.

Member of Central Nervous System Working Party (CNSWP) at the European Medicines Agency (EMA) since 2010.

BRANCH: CNS

INTERESTS:

CNS related diseases. Drug development including regulatory guidelines.

ASSOCIATIONS:

PREVIOUS INSTITUTIONS:

1986-1999 Consultant in Neurology, teacher and coordinator of medical students at Department of Neuroscience, Neurology unit, Uppsala University Hospital, Sweden.

1999-2007 Senior Research Physician, Department of Neurology, AstraZeneca, Sweden.

ABOUT RESEARCHES-ABSTRACTS AND BOOKS:

ORIGINAL PAPERS

1. Askmark H, Aquilonius S-M, Gillberg P-G, Hartvig P, Hilton-Brown P, Lindström B, Nilsson D, Stålberg E, Winkler T: Functional and pharmacokinetic studies of tetrahydroaminoacridine in patients with amyotrophic lateral sclerosis. *Acta Neurol Scand* 82: 253-258, 1990.
2. Lennernäs, H., Nilsson, D., Aquilonius, S.-M., Ahrenstedt, Ö., Knutson, L., Paalzow, L: The effect of L-leucine on the absorption of levodopa, studied by regional jejunal perfusion in man. *Br. J. Clin. Pharmac.*, 35, 243-250, 1993.
3. Bredberg E, Nilsson D, Johansson K, Aquilonius S-M, Johnels B, Nyström C, Paalzow L: Intraduodenal infusion of a water-based levodopa dispersion in optimization of the therapeutic effect in severe Parkinson's disease. *Eur. J. Clin. Pharmacol.*, 45, 117-122, 1993.
4. Nilsson D, Fagerholm U, Lennernäs H: The influence of net water absorption on the permeability of levodopa in the human jejunum. *Pharmaceutical Research*, 11, 1540-1544, 1994.
5. Nilsson D, Hansson L-E, Johansson K, Nyström C, Paalzow L, Aquilonius S-M: Long-term intraduodenal infusion of a water-based levodopa carbidopa dispersion in advanced Parkinson's disease. *Acta Neurol. Scand.*, 97, 175-183, 1998.
6. Nilsson D, Lennernäs H, Fasth K J, Sundin A, Tedroff J, Aquilonius S-M, Hartvig P, Långström B: Absorption of L-DOPA from the proximal small intestine studied in the rhesus monkey by positron emission tomography. *Eur J Pharm Sci.*, 7(3),185-9, 1999.
7. Fagerholm U, Nilsson D, Knutson L, Lennernäs H: Jejunal permeability in humans in vivo and rats in situ: investigation of molecular size selectivity and solvent drag. *Acta Physiol Scand.*, 165(3), 315-24, 1999.
8. Nilsson D, Nyholm D, Aquilonius SM: Duodenal levodopa infusion in Parkinson's disease--longterm experience. *Acta Neurol Scand.* 2001 Dec;104(6):343-8.
9. Andree B, Hedman A, Thorberg SO, Nilsson D, Halldin C, Farde L: Positron emission tomographic analysis of dose-dependent NAD-299 binding to 5-hydroxytryptamine-1A receptors in the human brain. *Psychopharmacology (Berl)*. 2003 Apr;167(1):37-45.
10. Wall A, Kågedal M, Bergstrom M, Jacobsson E, Nilsson D, Antoni G, Frandberg P, Gustavsson SA, Langstrom B, Yates R: Distribution of zolmitriptan into the CNS in healthy volunteers : a positron emission tomography study. *Drugs in R&D.* 2005; 6(3):139-47.
11. Wemer J, Cheng Y-F, Nilsson D, Reinholdsson I, Fransson B, Lanbeck Vallén K, Nyman L, Eriksson C, Björck S, Schulman S: Safety, tolerability and pharmacokinetics of escalating doses of NXY-059 in healthy young and elderly volunteers. *Current Medical Research and Opinion*

2006;22(9):1813–1823

12. Strid S, Nilsson D, Borgå O, Wemer J, Grahnén A: NXY-059 Does Not Significantly Interact With Furosemide in Healthy Volunteers. *Journal of Clinical Pharmacology*, 2006;46:1417-1425.

13. Nilsson D, Wemer J, Cheng Y-F, Reinholdsson I, Englund G, Schulman S, Egberg N: A randomized, double-blind, placebo-controlled phase I study to investigate the effect of NXY-059 on bleeding time and platelet function in healthy volunteers. *Journal of Clinical Pharmacology* 2007;47:264-272.

14. Huledal G, Nilsson D, Kågedal M, Reinholdsson I, Cheng Y-F, Svensson H, Borgå O, van Hout M: Effect of NXY-059, a novel neuroprotectant, on the pharmacokinetics of a single dose of digoxin in healthy subjects. Accepted for publication in *Current Medical Research and Opinion* 2007;23(7):1531–1539

15. Watabe M, Cheng Y-F, Nilsson D, Itoh Y, Kumagai Y: NXY-059 is well tolerated and demonstrates linear pharmacokinetics in Japanese subjects: a Phase I, placebo-controlled, randomized, doubleblind (within dose panels) study. *Current Medical Research and Opinion* 2007;23(8):1849–1857.

16. Cheng Y-F, Jiang J, Hu P, Reinholdsson I, Guo W, Åsenblad N and Nilsson D: Pharmacokinetics of 8-hour intravenous infusion of NXY-059: A Phase I, randomized, double-blind (within dose panels), placebo-controlled, study in healthy Chinese volunteers. *Clinical Therapeutics* 2008;30(12):2342-2353.

17. Örjan Lindhe, Per Almqvist, Matts Kågedal, Sven-Åke Gustafsson, Mats Bergström, Dag Nilsson, and Gunnar Antoni: Autoradiographic Mapping of 5-HT_{1B/1D} Binding Sites in the Rhesus Monkey Brain Using [carbonyl -11C]zolmitriptan. *International Journal of Molecular Imaging*, Volume 2011 (2011), Article ID 694179.

BRIEF REPORTS

1. Cheng Y-F, Strid S, Borgå O, Nilsson D, Wemer J: Active renal secretion of NXY-059, a novel neuroprotectant, is mediated via an organic acid transporter. *Journal of Clinical Pharmacology* 2007;47:909-914.

2. Kågedal M, Nilsson D, Huledal G, Reinholdsson I, Cheng Y-F, Åsenblad N, Pekar D, Borgå O: A study of organic acid transporter mediated pharmacokinetic interaction between NXY-059 and cefuroxime. *J Clin Pharmacol.* 2007 Aug;47(8):1043-8.

OUTSTANDING FEATURES: Long and broad experience of clinical neurology and drug development for CNS disorders, with high expertise of the regulatory framework for drug development in CNS diseases.