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Optimizing Treatment with Lurasidone in Patients with Schizophrenia: Results of a Randomized, Double-blind, Placebo-controlled Trial

A. Loebel[1], R. Silva[2], R. Goldman[3], K. Watabe[4], A. Pikalov[1], J. Cucchiaro[2], J. Kane[5]

[1]Clinical Development and Medical Affairs, Sunovion Pharmaceuticals Inc., Fort Lee, USA ; [2]Clinical Development, Sunovion Pharmaceuticals Inc., Fort Lee, USA ; [3]Clinical Development and Medical Affairs, Sunovion Pharmaceuticals Inc., Marlborough, USA ; [4]Biostatistics, Sunovion Pharmaceuticals Inc., Fort Lee, USA ; [5]Psychiatry, Hofstra North Shore-Long Island Jewish School of Medicine, Uniondale, USA

Introduction: Controlled data on optimization of dosing regimen for antipsychotics in schizophrenia is an unmet medical need.
Objective/Aims: To evaluate the efficacy of low dose lurasidone in schizophrenia; and to determine optimal dosing for patients not achieving improvement in Positive and Negative Syndrome Scale (PANSS) total score by week 2 of standard dosing.
Methods: Patients with schizophrenia were randomized to double-blind treatment with fixed daily doses of lurasidone 18.5 mg (for 6 wks; N=101), 74 mg (for 2 wks; N=198), or placebo (for 6 wks; N=112). After 2 weeks of treatment, patients in the 74 mg group with <20% PANSS improvement were re-randomized to continue on the 74 mg dose, or increase to a dose of 148 mg, for the next 4 wks.
Results: Lurasidone 18.5 mg did not demonstrate significant improvement vs. placebo at Week 6 (-17.6 vs -14.5; *P*=0.25). In the group with <20% PANSS improvement after 2 weeks (N=95), titration to lurasidone 148 mg resulted in significantly greater improvement in PANSS total score at Week 6 compared with 4 additional weeks of treatment at the 74 mg dose (-16.6 vs. -8.9; p=0.023).
Conclusions: This trial supports the 37 mg/d dose of lurasidone as minimally effective dose in patients with acute schizophrenia consistent with evidence from previous studies. Increasing the dose of lurasidone to 148 mg/d after 2 weeks of nonresponse at 74 mg/d resulted in a significant efficacy advantage with important potential implications for clinical practice.
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