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The calming down of emotional ferris wheel, Bipolar disease: Demonstration of anti-manic efficacy of endoxifen in Bipolar I disorder patients

Protein kinase C (PKC) activity is increased in frontal cortex of subjects with bipolar affective disorder. Endoxifen, an active metabolite of tamoxifen, was recently demonstrated to inhibit PKC1. We report for the first time the anti-manic effect of endoxifen in patients with bipolar I disorder (BPD I) with current manic or mixed episode. The efficacy was evidenced by change from baseline on total scores of mania [e.g., Young Mania Rating Scale (YMRS)] measures. In a double-blind, active-controlled study, 84 subjects with BPD I were randomly assigned to receive endoxifen (4 mg/day or 8 mg/day) or divalproex (1000 mg/day) in a 2:1 ratio. Patients orally administered at 4 or 8 mg/day endoxifen showed significant improvement in mania assessed by the YMRS as early as 4 days. The effect remained significant throughout the 21-day period. At study end point, YMRS scores showed the response rates were 44.44% and 64.29% at 4 and 8 mg/day of endoxifen treatment respectively. The Exposure-Response (PK-PD) analysis shows dose proportionality of endoxifen2. Thus, endoxifen has been shown as a promising anti-manic or mood stabilizing agent.

Biography

Ateeq Ahmad, is vice president for science & technology at Jina pharmaceuticals, Inc., USA. Prior to joining Jina in 2006, He worked at Neopharm, Inc., Pharmacia (Searle), Sanofi, J &J, Medarex, Biotherapeutics and National Institutes of Health. He has more than 30 years of experience in drug discovery, drug targeting, therapeutic proteins, immunotoxins, liposomes and clinical pharmacology. Currently, he is directing drug development program including safety assessment, efficacy evaluation and pharmacokinetics of drug candidates for cancer therapeutics and neurological disorders. He has authored 61 original articles in peer reviewed scientific journals.

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