Phase II Trial for Schizophrenia Treatment Yields Positive Results

Biopharmaceutical company Intra-Cellular Therapies, Inc. has announced positive topline results from a randomized, double-blind, placebo- and active-controlled Phase II clinical trial of its lead drug candidate, ITI-007, in patients with acutely exacerbated schizophrenia.

In this trial, 335 patients were randomized to receive one of four treatments: 60 mg ITI-007, 120 mg ITI-007, 4 mg risperidone (Risperdal®) (active control), or placebo in a 1:1:1:1 ratio. Patients received the study treatment orally once daily in the morning for 28 days. Of those randomized, 311 patients were included in the intent-to-treat primary analysis.

Seventy-four percent of randomized participants completed trial participation. Only 19% discontinued during the 28-day study treatment period, and an additional 7% completed study treatment but were lost to follow up.

The study met its pre-specified primary endpoint: ITI-007 at a dose of 60 mg improved symptoms associated with schizophrenia from baseline to Day 28 as measured by a statistically significant (p = 0.017) and clinically meaningful decrease in the Positive and Negative Syndrome Scale (PANSS) total score, compared to placebo.

The improvement in the total PANSS score in the 120-mg dose group, however, did not reach statistical significance. Researchers believe sedation, the most frequent side effect in the 120-mg dose group, may have interfered with the ability to detect an efficacy signal at this dose administered once daily in the morning.


FDA Approves First Generic Versions of Cymbalta

The U.S. Food and Drug Administration has approved the first generic versions of Cymbalta® (duloxetine delayed-release capsules), a prescription medicine used to treat depression and other conditions. Duloxetine will be marketed in various strengths.

Duloxetine and other antidepressant drugs have a boxed warning that describes the increased risk of suicidal thinking and behavior during initial treatment in children, adolescents, and young adults ages 18 to 24. It also points out that data do not show this increased risk in those older than 24 and that patients 65 and older who take antidepressant agents have a decreased risk of suicidal thinking and behavior. Duloxetine must be dispensed with a patient medication guide that describes important information about the drug’s uses and risks.


Phase III Study for Depression Failed to Meet Primary Endpoint

Eli Lilly and Company announced that results from three studies of edivoxetine did not meet the primary study objective of superior efficacy in depression after 8 weeks of treatment.

In 2010, Lilly launched the Phase III program for edivoxetine—a potent and highly selective norepinephrine reuptake inhibitor—to assess its benefits and risks as an add-on therapy in patients with major depressive disorder (MDD). The Phase III program specifically focused on meeting the unmet needs of patients with major depression who had achieved only a partial response to treatment with a selective serotonin reuptake inhibitor (SSRI). In these three trials, patients remained on SSRI treatment and additionally received either edivoxetine or placebo.

When added to an SSRI, edivoxetine did not separate from placebo on the Montgomery-Asberg Depression Rating Scale in three acute randomized placebo-controlled Phase III studies.

Although the safety and tolerability of edivoxetine was consistent with previous studies, the efficacy results do not support a regulatory submission for adjunctive treatment in patients with MDD. Data from all three studies will be disclosed in appropriate scientific forums in 2014.