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**CEDARS-SINAI RESEARCHERS PUBLISH FIRST LARGE-SCALE STUDY ADDRESSING AUGMENTATION TREATMENT FOR RESISTANT MAJOR DEPRESSIVE DISORDER; RESULTS OFFER NEW HOPE FOR THE CHRONICALLY DEPRESSED**

**LOS ANGELES (August 4, 2006)** – In the first large-scale study of its kind, researchers at Cedars-Sinai found that people suffering from resistant major depressive disorder who don't respond to standard antidepressants can benefit when the drug therapy is augmented by a broad spectrum psychotropic agent, even when treated for a brief period of time. The study led by Mark Hyman Rapaport, M.D., chair of the department of psychiatry at Cedars-Sinai, was recently published in *Neuropsychopharmacology AOP*.

Although physicians have used a two-pronged drug therapy approach to boost the effectiveness of antidepressants in depressed patients who show resistance to the standard SSRI (Selective Serotonin Reuptake Inhibitor) antidepressants such as Prozac and Zoloft, this is the first time continuation of supplementary treatment was studied in severely ill individuals.

The study, which tracked a group of depressed patients who showed resistance to the standard SSRI antidepressant therapy found that those characterized as less severely ill only needed to stay on the broad spectrum psychotropic agent Risperidone for a brief period of time to experience lasting benefits; making their antidepressant medication work effectively. Those depressed patients who were characterized as more severely ill, however, needed to continue Risperidone on an ongoing basis to experience the same level of effectiveness.

Approximately 40 percent of people who suffer from depression cannot get better with the use of antidepressants or psychotherapy. Their inability to improve can cause problems with many aspects of their lives, including work and family relationships, and can become expensive to treat.

"The implications of our research shows that a certain subset of individuals with chronic depression who don't respond to standard treatment with antidepressant medication could benefit from a brief period of supplementary therapy," said Dr. Rapaport, the study's principal investigator.

"This type of adjunctive treatment is likened to how a patient with a severe autoimmune disease who is on anti-inflammatory medication is given a steroid to quiet his/her symptoms when they flare up," Rapaport continued. "Typically, these patients don't need to stay on the steroid indefinitely for it to be effective in the long-term."

Patients with major depressive disorder who did not respond to at least one pharmacological treatment for major depression participated in the study. On average, the majority of patients had not responded to more than two medications, and the mean length of illness had been almost two years.

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Subjects were treated with Citalopram, up to 60 milligrams per day for four to six weeks. Those who did not have at least a 50 percent reduction in symptoms were offered the opportunity to have unblinded standard treatment with a broad spectrum psychotropic agent (atypical antipsychotic) Risperidone at up to 2 milligrams per day.

The majority of individuals participated in this phase during which both researchers and patients were aware of the drug and dosage, and almost 60 percent of people who had Risperidone augmentation met criteria for being in remission from depression by the end of four to six weeks of this treatment. At that point, individuals entered a double-blind portion of the protocol where Risperidone was either continued or the patient was placed on a placebo.

“We are very encouraged by this research. Treatment-resistant depression is associated with the grave risk of increased morbidity and mortality and with a severely decreased quality of life. It is one of the most pressing public health needs that we face as a society,” Rapaport said. “We hope this study will stimulate other researchers to pursue investigating the need for continuation of supplemented therapies.”

Major depressive disorder, characterized by sadness, sleeplessness, fatigue, feelings of worthlessness, and other debilitating symptoms is the world’s most silent public health disorder. Depression among 18-45 year-olds is the leading cause of disability worldwide. The presence of depression increases one’s risk for heart attack, stroke, and can cause diabetes to worsen. In addition, depression increases one’s risk of suicide; almost twice as many people die from suicide than homicide in the United States.

The abstract of the study *Effects of Risperidone Augmentation in Patients with Treatment-Resistant Depression: Results of Open-Label Treatment Followed by Double-Blind Continuation*, can be accessed on the *Neuropsychopharmacology* website:  
<http://www.nature.com/npp/journal/vaop/ncurrent/abs/1301113a.html>.

Dr. Mark Hyman Rapaport was the study’s principal investigator. Co-principal investigators were Charles B. Nemeroff, Ph.D., M.D. and Martin B. Keller, M.D. The research was funded by Janssen Pharmaceutica, and by a Cedars-Sinai grant.

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