

Phase I/II Trial Begins for Potential Dementia Drug

Intra-Cellular Therapies, Inc., a biopharmaceutical company focused on the development of therapeutics for central nervous system disorders, has initiated a Phase I/II clinical trial for ITI-007-200 to evaluate the safety, tolerability, and pharmacokinetics of low doses of its lead drug candidate, ITI-007, in healthy geriatric participants and in patients with dementia, including Alzheimer's disease.

The ITI-007-200 trial is planned to be conducted in two parts. Part 1 is a randomized, double-blind, placebo-controlled multiple ascending dose evaluation of ITI-007 in healthy geriatric participants. In each cohort in Part 1, it is anticipated that 10 participants will be randomized to receive ITI-007 ($n = 8$) or placebo ($n = 2$) for 7 days. In Part 2, it is anticipated that 12 patients with dementia will be randomized to receive ITI-007 ($n = 9$) or placebo ($n = 3$) for 7 days. The number of cohorts in each part may be adjusted based on results. Safety, tolerability, and pharmacokinetic data will be determined. Exploratory pharmacodynamic endpoints will be included to assess feasibility of measuring agitation, sedation, sleep, and cognition in potential future trials. Initial data from the trial are expected to be available in the second half of 2014.

At the lowest doses studied to date, ITI-007 has been demonstrated to act primarily as a potent 5-HT_{2A} serotonin receptor antagonist. As the dose is increased, additional benefits are derived from the engagement of additional drug targets, including modest dopamine receptor modulation and modest inhibition of serotonin transporters. Scientists at Intra-Cellular Therapies believe that combined interactions at these receptors may provide additional

Single-Injection Treatment Approved for Osteoarthritis of the Knee

The U.S. Food and Drug Administration (FDA) has approved Anika Therapeutics, Inc.'s Monovisc[®], a single-injection supplement to synovial fluid of the osteoarthritic joint, used to treat pain and improve joint mobility in patients with osteoarthritis (OA) of the knee. Monovisc is the first FDA-approved single-injection product with hyaluronate from a non-animal source. It is comprised of a sterile, clear, biocompatible, resorbable, viscoelastic fluid composed of partially cross-linked sodium hyaluronate (NaHA) in phosphate buffered saline.



© DePuy Synthes Mitek Sports Medicine

Anika has marketed Monovisc internationally since 2008. The product is currently sold in a variety of territories, including Canada, the United Kingdom, and several countries in the Middle East, Europe, and Asia.

The FDA approval of Monovisc is based on safety and effectiveness data from a randomized, controlled, double-blind multicenter pivotal U.S. clinical study encompassing a total of 369 patients with OA of the knee at 31 centers in the United States and Canada. The objective of the study was to assess the safety and effectiveness of Monovisc for the treatment of joint pain. Patients were randomized to either Monovisc or control (saline injection) and were evaluated for improvement in pain, as measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at follow-up assessments out to 26 weeks. The primary effectiveness analysis compared the proportion of Monovisc patients achieving a greater improvement from baseline in WOMAC pain score versus control through 12 weeks. The safety analysis showed Monovisc had an extremely low rate of adverse events, with no serious adverse events associated with Monovisc.

Source. "FDA Approves Monovisc." (2014, February 25). Retrieved March 27, 2014, from <http://bit.ly/1hAQR2>.

benefits above and beyond selective 5-HT_{2A} antagonism for treating agitation, aggression, and sleep disturbances in diseases that include dementia, Alzheimer's disease, and autism spectrum disorders, while avoiding many of the side effects associated with more robust dopamine receptor antagonism. As the dose of ITI-007 is further increased, leading to moderate dopamine receptor modulation, inhibition of serotonin transporters, and indirect glutamate modulation, these actions comple-

ment the complete blockade of 5-HT_{2A} serotonin receptors. In this dose range, Intra-Cellular Therapies believes that ITI-007 may be useful in treating the symptoms associated with schizophrenia, bipolar disorder, major depressive disorder, and other neuropsychiatric diseases.

Source. "Intra-Cellular Therapies Announces Initiation of Phase I/II Clinical Trial for ITI-007 in Healthy Geriatric Subjects and Patients with Dementia, Including Alzheimer's Disease." (2014, March 3). Retrieved March 26, 2014, from <http://prn.to/1m6K4G2>. doi:10.3928/00989134-20140331-89