Intra-Cellular Therapies Announces Expansion of its Pipeline with the Introduction of a New Molecular Entity, ITI-1284

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ITI-1284 is a deuterated form of lumateperone delivered sublingually as an orally disintegrating tablet (ODT-SL). ITI-1284 ODT-SL may offer pharmacologic benefits and ease-of-use for patients, particularly in elderly populations.

Phase 1 single ascending dose and multiple ascending dose studies have been completed in healthy volunteers including elderly subjects > than 65 years of age.

Company plans to develop ITI-1284 for the treatment of behavioral disturbances in dementia, dementia-related psychosis, and certain depressive disorders in the elderly.

NEW YORK, Feb. 24, 2021 (GLOBE NEWSWIRE) -- Intra-Cellular Therapies, Inc. (Nasdaq: ITCI), a biopharmaceutical company focused on the development and commercialization of therapeutics for central nervous system (CNS) disorders, today announced the expansion of its pipeline with ITI-1284 ODT-SL. ITI-1284 is a deuterated form of lumateperone, a new molecular entity formulated as an oral disintegrating tablet for sublingual administration. Following recent completion of its Phase 1 program, the Company plans to develop ITI-1284 ODT-SL for the treatment of behavioral disturbances in patients with dementia, the treatment of dementia-related psychosis and the treatment of certain depressive disorders in the elderly.

ITI-1284 ODT-SL is formulated as an oral solid dosage form that dissolves almost instantly when placed under the tongue, allowing for ease of use in the elderly and may be particularly beneficial for patients who have difficulty swallowing conventional tablets. ITI-1284 ODT-SL has been developed in collaboration with Catalent using its proprietary Zydis® ODT (orally disintegrating tablet) fast-dissolving formulation.

Our recently completed Phase I program found that ITI-1284 ODT-SL was rapidly absorbed into the systemic circulation, was metabolically stable, and resulted in high systemic exposure. Our Phase 1 single and multiple ascending dose studies in healthy volunteers and healthy elderly volunteers (> than 65 years of age) evaluated the safety, tolerability and pharmacokinetics of ITI-1284. In these studies, there were no reported serious adverse events in either age group. In the elderly cohort, reported adverse events were infrequent with the most common adverse event being transient dry mouth (mild).

Based on these studies, the Company plans to initiate Phase 2 studies evaluating ITI-1284 ODT-SL for the treatment of behavioral disturbances in dementia, dementia-related psychosis, and certain depressive disorders in the elderly.

About ITI-1284

ITI-1284 is a deuterated form of lumateperone where carbon-deuterium bonds strategically replace carbon-hydrogen bonds. ITI-1284 has high affinity for serotonin 5-HT_{2A} receptors and moderate affinity for dopamine D_2 and D_1 receptors, and the serotonin transporter.

ITI- 1284 is an investigational agent and has not been approved for use for any indication.

About Intra-Cellular Therapies

Intra-Cellular Therapies is a biopharmaceutical company founded on Nobel prize-winning research that allows us to understand how therapies affect the inner-workings of cells in the body. The company leverages this intracellular approach to develop innovative treatments for people living with complex psychiatric and neurologic diseases. For more information, please visit www.intracellulartherapies.com.

Forward-Looking Statements

This news release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, the therapeutic value, clinical and non-clinical development plans and commercial potential of our drug product candidates; the progress, timing and results of our clinical trials and preclinical studies; our beliefs about the extent to which the results of our clinical trials and preclinical studies to date support new drug application filings for product candidates; the safety and efficacy of our product development candidates; our beliefs about the potential uses and benefits of our drug product candidates; and development efforts and plans under the caption "About Intra-Cellular Therapies." All such forward-looking statements are based on management's present expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These risks and uncertainties include but are not limited to the following: our current and planned clinical trials or other studies for our product candidates may not be successful or may take longer and be more costly than anticipated; product candidates that appeared promising in earlier research and clinical trials may not demonstrate safety and/or efficacy in larger-scale or later clinical trials; our proposals with respect to the regulatory path for our product candidates may not be acceptable to the FDA; our reliance on collaborative partners and other third parties for development of our product candidates; the COVID-19 pandemic may negatively impact the conduct of, and the timing of enrollment, completion and reporting with respect to, our clinical trials; any other impacts on our business as a result of or related to the COVID-19 pandemic; and the other risk factors detailed in our public filings with the Securities and Exchange Commission. All statements contained in this press release are made only as of the date of this press release, and we do not intend to update this information unless required by law.

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