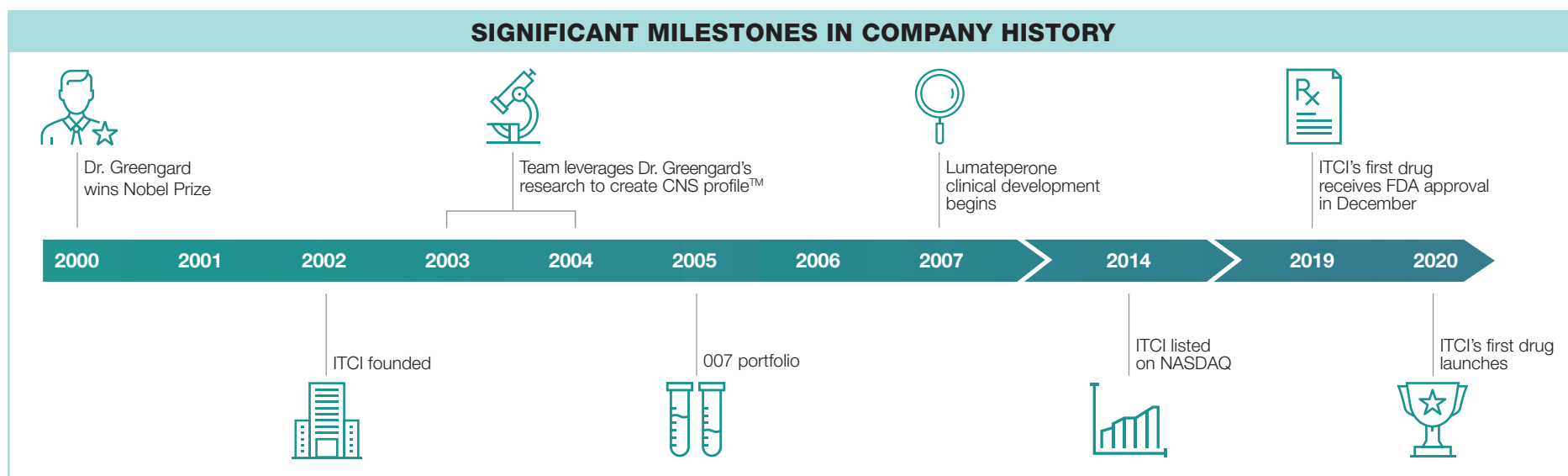


SIGNIFICANT MILESTONES IN COMPANY HISTORY



Important Safety Information (continued)

Warnings & Precautions: Antipsychotic drugs have been reported to cause:

- **Falls.** CAPLYTA may cause somnolence, postural hypotension, and motor and/or sensory instability, which may lead to falls and, consequently, fractures and other injuries. Assess patients for risk when using CAPLYTA.
- **Seizures.** Use CAPLYTA cautiously in patients with a history of seizures or with conditions that lower seizure threshold.
- **Potential for Cognitive and Motor Impairment.** Advise patients to use caution when operating machinery or

motor vehicles until they know how CAPLYTA affects them.

- **Body Temperature Dysregulation.** Use CAPLYTA with caution in patients who may experience conditions that may increase core body temperature such as strenuous exercise, extreme heat, dehydration, or concomitant anticholinergics.
- **Dysphagia.** Use CAPLYTA with caution in patients at risk for aspiration.

Drug Interactions: Avoid concomitant use with CYP3A4 inducers and moderate or strong CYP3A4 inhibitors.

Special Populations: Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for

extrapyramidal and/or withdrawal symptoms following delivery. Breastfeeding is not recommended. Avoid use in patients with moderate or severe hepatic impairment.

Adverse Reactions: The most common adverse reactions in clinical trials with CAPLYTA vs. placebo were somnolence/sedation (24% vs. 10%) and dry mouth (6% vs. 2%).

Please see accompanying full Prescribing Information, including **Boxed Warning**.

CAPLYTA is a trademark of Intra-Cellular Therapies, Inc. All other trademarks and registered trademarks are property of their respective owners. ©2020 Intra-Cellular Therapies, Inc. All rights reserved. 02/2020 US-LUM-2000051



BUILT ON NOBEL PRIZE–WINNING SCIENCE

The company was founded in 2002 on Dr. Paul Greengard's Nobel Prize–winning research on intracellular signaling. This research changed our understanding of how cells interact and communicate with each other in both normal and disease states. Intra-Cellular Therapies leverages this approach to look at the brain to identify and develop medicines to treat complex psychiatric and neurological diseases.



Our mission is to develop innovative treatments to improve the lives of individuals suffering from neuropsychiatric and neurologic disorders in order to reduce the burden on patients and their caregivers.

CAPLYTA[™]
(lumateperone) capsules
42 mg

Approved For Adults With Schizophrenia

Important Safety Information

Boxed Warning: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. CAPLYTA is not approved for the treatment of patients with dementia-related psychosis.

Contraindications: CAPLYTA is contraindicated in patients with known hypersensitivity to lumateperone or any components of CAPLYTA.

Warnings & Precautions: Antipsychotic drugs have been reported to cause:

- **Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis**, including stroke and transient ischemic attack. See Boxed Warning above.

- **Neuroleptic Malignant Syndrome**, which is a potentially fatal reaction. Signs and symptoms include: hyperpyrexia, muscle rigidity, delirium, autonomic instability, elevated creatinine phosphokinase, myoglobinuria (and/or rhabdomyolysis), and acute renal failure. Manage with immediate discontinuation of CAPLYTA and close monitoring.
- **Tardive Dyskinesia**, a syndrome of potentially irreversible, dyskinetic, and involuntary movements which may increase as the duration of treatment and total cumulative dose increases. Discontinue CAPLYTA if clinically appropriate.
- **Metabolic Changes**, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. Measure weight and assess fasting plasma glucose and lipids when initiating CAPLYTA and monitor periodically during long-term treatment.

- **Leukopenia, Neutropenia, and Agranulocytosis (including fatal cases)**. Perform complete blood counts in patients with pre-existing low white blood cell count (WBC) or history of leukopenia or neutropenia. Discontinue CAPLYTA if clinically significant decline in WBC occurs in absence of other causative factors.
- **Orthostatic Hypotension and Syncope**. Monitor heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease.

Please see additional Important Safety Information on back and accompanying full Prescribing Information, including **Boxed Warning**.