Recognify Life Sciences Provides Update on Phase 2b Trial of Inidascamine in Patients with Cognitive Impairment Associated with Schizophrenia

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- Initial results demonstrate numerical improvement of cognitive and functional measures with inidascamine across both active treatment arms compared to placebo, but did not meet statistical significance on the primary endpoint
- Inidascamine continues to exhibit a favorable safety and tolerability profile
- Full data set, including secondary endpoints and subgroup analyses will be forthcoming

SOUTH SAN FRANCISCO, July 25, 2025 (GLOBE NEWSWIRE) -- Recognify Life Sciences, a clinical-stage biotech company focused on developing treatments for cognitive impairment, today announced that its randomized, double-blind, placebo-controlled Phase 2b clinical trial evaluating inidascamine (formerly RL-007) in patients with cognitive impairment associated with schizophrenia (CIAS) did not meet its primary endpoint.

While the study did not achieve statistical significance on its primary endpoint of improvement on the Measurement and Treatment Research to Improve Cognition in Schizophrenia Consensus Cognitive Battery (MCCB) neurocognitive composite score at Week 6, inidascamine demonstrated a modest but consistent numerical improvement across the overall MCCB neurocognitive composite and multiple individual subdomains, including Symbol Coding, Speed of Processing and Verbal Learning (immediate recall). Directionally positive effects were also observed on the Virtual Reality Functional Capacity Assessment Tool (VRFCAT), a measure of real-world functional cognitive capacity.

Inidascamine was well-tolerated, with a favorable safety profile consistent with previous studies. Importantly, no evidence of sedation, weight gain, or extrapyramidal symptoms was observed, which are side effects commonly associated with treatments used in people living with schizophrenia.

Matt Pando, PhD, Chief Executive Officer and Co-Founder of Recognify Life Sciences, commented: *“Although we are disappointed that the study did not reach statistical significance on the primary efficacy endpoint, we are encouraged by the consistency of improvement signals across multiple cognitive and functional measures as well as replication on specific subsets of the cognitive measures; namely, symbol coding and verbal memory. These findings reinforce our commitment to addressing the significant unmet needs of cognitive impairment associated with numerous mental health and neurodegenerative conditions. Inidascamine continues to exhibit a strong safety profile, and we look forward to analyzing the full data set to better understand the outcome and inform potential next steps for the program.”*

The randomized, placebo-controlled, double-blind, Phase 2b clinical study enrolled 242 patients across the United States and Europe (NCT05686239). The trial evaluated the efficacy, safety, and tolerability of two doses of inidascamine versus placebo over a six-week treatment period. A comprehensive analysis of remaining secondary and exploratory endpoints, including subgroup analyses, is ongoing to determine whether there are identifiable responder populations or mechanistic insights that may guide future development.

Keith Nuechterlein, PhD, Distinguished Professor in the UCLA Department of Psychiatry and Biobehavioral Sciences and co-chair of the MATRICS Neurocognition Committee, commented upon seeing these results: “*Developing treatments for cognitive impairment in schizophrenia is a complex challenge that requires persistence and innovation. I am encouraged by the inidascamine topline results showing consistent directional tendencies for improvement and look forward to seeing the full set of results.”*

Recognify plans to present additional results from the study at upcoming scientific meetings and will continue to evaluate strategic options for inidascamine based on the totality of data.

Srinivas Rao, MD, PhD**,** Chief Executive Officer and Co-Founder of atai Life Sciences, added: *“CIAS remains a challenging therapeutic area with a significant unmet need. While we believe these results support the continued development of inidascamine by Recognify for CIAS as well as its potential application in other indications, as previously communicated, we intend to allocate atai’s resources on our wholly owned pipeline of transformative psychedelic product candidates focused on affective disorders."*

About Inidascamine
Inidascamine, formerly RL-007, is an orally available compound, with unique mechanisms of action for the treatment of cognitive impairment, that modulates cholinergic, glutamatergic and GABA-B receptors, thereby putatively altering the excitatory/inhibitory balance in the brain to produce pro-cognitive effects. It has previously been evaluated in ten clinical studies, including one in the CIAS indication, with over 600 unique participants dosed to date. Clinical studies of inidascamine suggest improvement in

cognitive performance, particularly for verbal learning and memory and processing speed.

About Schizophrenia and CIAS
Schizophrenia is a mental health disorder primarily characterized by hallucinations, delusions, and disordered thinking. This condition effects over 21 million people globally and approximately 2.4 million people in the United States, with around 300,000 new cases being diagnosed each year in the US. Cognitive deficits -present in approximately 80% of patients, is a core feature of the illness and contributes significantly to long-term disability and impairments in daily functioning. There are presently no effective pharmaceutical treatments approved for CIAS, representing a high unmet clinical need.

About Recognify Life Sciences, Inc.
Recognify Life Sciences is a clinical-stage biotech company on a mission to provide pro-cognitive treatments solutions to mental health and neurodegenerative disorders. The company is a strategic investment of atai Life Sciences. For more information about Recognify, please visit www.recognify.life.

About atai Life Sciences
atai is a clinical-stage biopharmaceutical company on a mission to develop highly effective mental health treatments to transform patient outcomes. atai's pipeline of psychedelic-based therapies includes BPL-003 (mebufotenin benzoate) for treatment-resistant depression (TRD), which is being advanced through a planned strategic combination with Beckley Psytech Limited; VLS-01 (buccal film DMT) also for TRD; and EMP-01 (oral R-MDMA) for social anxiety disorder. All three programs are in Phase 2 clinical development. It is also advancing a drug discovery program to identify novel, non-hallucinogenic 5-HT2AR agonists for TRD. These programs aim to address the complex nature of mental health providing commercially scalable interventional psychiatry therapies that can integrate seamlessly into healthcare systems. For the latest updates and to learn more about atai's mission, visit www.atai.com or follow the Company on LinkedIn and on X.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "initiate," "could," "would," "project," "plan," "potentially," "preliminary," "likely," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words. All statements in this press release other than statements of historical fact are forward-looking statements, including, express or implied statements relating to, among other things: statements regarding Recognify Life Science's inidascamine (formerly RL-007) studies, data, or related strategic plans and objectives of management for future operations, capital expenditures and capital allocation. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond our control and which could cause actual results, levels of activity, performance, or achievements to differ materially from those expressed or implied by these forward-looking statements.

Forward-looking statements are neither promises nor guarantees, but involve known and unknown risks and uncertainties that could cause actual results to differ materially from those projected, including, without limitation, the important factors described in the section titled "Risk Factors" in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC"), as such factors may be updated from time to time in atai's other filings with the SEC. atai disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release, other than to the extent required by applicable law.

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