EuMentis Therapeutics Plans to Initiate Phase 2 study of EM-221, a PDE10A Inhibitor, for Treatment of Tourette Syndrome

Eumentis is Developing Novel Neurocircuit Selective Medicines to Treat Childhood Neurodevelopmental Disorders

NEWTON, MASSACHUSETTS, UNITED STATES, March 24, 2022 /EINPresswire.com/ -- EuMentis Therapeutics, Inc. (“EuMentis” or the “Company”), a clinical-stage pharmaceutical company developing neurocircuit-selective medicines to treat neurodevelopmental disorders, announced today that it will initiate a phase 2 clinical study of EM-221 for the treatment of Tourette Syndrome. EM-221 is a novel, highly selective phosphodiesterase 10A (“PDE10A”) inhibitor in-licensed from Mochida Pharmaceuticals Co., Ltd. in Japan. EM-221 is expected to act selectively to modulate the dopamine D2 pathway in the striatum, similarly to antipsychotic drugs which are effective, but without significant safety and tolerability problems such as their metabolic side effects. The current IP portfolio for EM-221 includes multiple issued and pending patents covering substance, pharmaceutical composition, and manufacturing.

“Licensing this highly differentiated potential best-in-class PDE10A inhibitor strengthens our commitment to developing innovative therapeutics for the treatment of childhood neurodevelopmental conditions,” said Mark Tepper, Ph.D., Chief Executive Officer of EuMentis. “We are excited to advance the development of EM-221 following the work done by Mochida which showed excellent safety and tolerability of this compound in phase 1 clinical trials and best-in-class target engagement of PDE10A. We expect to initiate phase 2 clinical trials with EM-221 in Tourette Syndrome in 3rd quarter of 2022.”

“The selective expression of PDE10A in the striatum provides a unique opportunity to target the dopamine D2 inhibitory pathway without the side effects of antipsychotic drugs caused by their broad activity throughout the brain,” commented Randall Marshall, MD, Chief Medical Officer of EuMentis. “We are excited about EM-221’s potential to modulate this highly selective and

clinically validated target. The safety of EM-221 has been established in 3 phase 1 studies, and we plan to initiate clinical studies to advance EM-221 toward becoming a new, better and much-needed therapeutic option for patients with Tourette syndrome."

Donald Gilbert, MD, Professor, University of Cincinnati, Cincinnati Children's Hospital, commented "I see Tourette Syndrome patients every week in our clinic that are in need of effective, safer and better tolerated therapies than the ones we have today. I am pleased to work with EuMentis to develop EM-221 for this neglected neurodevelopmental condition, which can have a serious impact on the functioning and well-being of patients."

Keith Coffman MD, Associate Professor of Pediatrics, University of Missouri-Kansas City School of Medicine, added "I am pleased to see a truly novel compound being studied for the treatment of Tourette Syndrome. I am looking forward to working with EuMentis on this phase 2 trial of a PDE10A inhibitor for this common neurodevelopmental movement disorder."

Significant Market Opportunities for EM-221

EM-221, EuMentis' lead drug candidate, is a synthetic, small-molecule, orally active, highly selective PDE10A inhibitor with picomolar potency and >100,000-fold selectivity vs other phosphodiesterases. It acts to elevate cAMP levels in the spiny motor neurons of the striatum, which result in increased inhibitory signaling from the dopamine D2 pathway. Mochida has completed Phase 1 studies including SAD, MAD, and target occupation studies. A Phase 2 study of EM-221 for the treatment of Tourette Syndrome is planned to begin in the 3rd quarter of 2022.

Tourette Syndrome

Tourette Syndrome is a neurological disorder with typical onset in childhood, characterized by repetitive, stereotyped, involuntary movements and vocalizations called tics. Tics can be simple, such as eye blinking, grimacing, or spoken words or phrases, or complex, such as hopping, bending, twisting, and sometimes self-harm behaviors. Functional impairment can be severe, and other simultaneous disorders are common.
FDA-approved therapies are all antipsychotics, which modulate dopaminergic and other pathways throughout the brain but have serious safety and tolerability liabilities in children. Tourette Syndrome affects approximately 300,000 patients in the U.S., Europe and Japan combined and is considered an orphan drug indication in the US.

About EuMentis

EuMentis Therapeutics, Inc. is a clinical-stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat neurodevelopmental conditions with high unmet need. The Company's most advanced product candidate, EM-221, is a novel, synthetic oral PDE10A inhibitor designed to inhibit the dopamine D2 pathway specifically

in the striatum. EuMentis is also developing an uncompetitive fast-off NMDA receptor antagonist for the treatment of autism spectrum disorder patients with elevated brain glutamate levels as determined by MR spectroscopy.

For more information, please visit www.EuMentisTx.com and connect with the Company on Twitter, LinkedIn, and Facebook.

About Mochida

Mochida Pharmaceutical Co., Ltd. is a publicly held, Japanese pharmaceutical company which has been committed to research and development of innovative pharmaceutical products since its establishment thereby providing distinctive medicines to the medical field. Currently, the core pharmaceutical business focuses resources on the targeted areas of cardiovascular medicine, obstetrics and gynecology, psychiatry and gastroenterology, while also providing medicine for intractable disease as well as generics including biosimilars, to meet medical needs.
For more information, please visit www.mochida.co.jp/english/.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release.

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