Epirium Bio Receives FDA Orphan-Drug Designation for EB 002 ((+)-Epicatechin) for the Treatment of Duchenne and Becker Muscular Dystrophy

San Diego, Calif. -- (BUSINESS WIRE) – April 14, 2020 – Epirium Bio Inc., a clinical-stage biopharmaceutical company focused on mitochondrial biogenesis and complementary therapeutic approaches as a means to addressing neuromuscular diseases and neurodegenerative diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan-drug designation for its unique, orally available, synthetic flavanol EB 002 ((+)-epicatechin) for the treatment of Duchenne and Becker muscular dystrophy. Orphan-drug designation is granted to support development of medicines for patient populations fewer than 200,000 people in the U.S. The company will initially focus on advancing its treatment in Becker muscular dystrophy.

“Epirium’s development program focuses on harnessing a differentiated therapeutic approach that may concurrently address several key drivers of serious diseases,” said Ransi Somaratne, M.D., Epirium’s chief medical officer. “Our initial emphasis on Becker muscular dystrophy stems from our research demonstrating that EB 002 may stimulate mitochondrial biogenesis, leading to the restoration of tissue bioenergetics, while upregulating production of key proteins which may lead to improved muscle structure and function.”

Becker muscular dystrophy is a rare genetic, degenerative disease that causes progressive muscle weakening and loss, primarily affecting skeletal and cardiac muscles. It is estimated to affect between 1 in 18,000 and 1 in 30,000 male births.

“We are delighted that the data presented on EB 002 supported the FDA’s grant of an orphan-drug designation,” said Russell Cox, Epirium’s chief executive officer. “This is an important milestone for the development of our potential treatment for Becker muscular dystrophy patients, for whom there are no specific treatment options. Our hope is that this designation along with our robust clinical development program will lead to potential new therapies in diseases where they are urgently needed. “

About Epirium

Epirium is a clinical stage biopharmaceutical company that has developed unique insights related to the biology of mitochondrial biogenesis and tissue regeneration, potentially resulting in novel and clinically significant therapeutic approaches to currently intractable neuromuscular and neurodegenerative diseases. The Company has identified and established an IP-protected platform of small molecules that constitute a new class of therapeutics with the potential to stimulate mitochondrial biogenesis and tissue regeneration. Epirium intends to advance its first clinical candidate (EB 002) this year, initially in Becker muscular dystrophy, followed by drug development targeting other progressive neuromuscular and neurodegenerative disorders associated with mitochondrial depletion. To learn more, please visit www.epirium.com.

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