

EPI-743 Investigator Team to Report on Edison Mitochondrial Drug

FDA allows broadened diagnostic criteria for expanded access trial enrollment

Boston, MA. June 8, 2011 - Edison Pharmaceuticals announced today that enrollment criteria for the EPI-743 Expanded Access Protocol EPI-2009-1 has been amended and will now include patients with genetic diagnosis and those that meet specific clinical criteria, absent genetic confirmation, are eligible. Details on inclusion criteria can be found at clinicaltrials.gov.

EPI-743 is an experimental drug being developed by Edison for inherited mitochondrial disease. Since June 2010, the United States Food and Drug Administration (FDA) has allowed investigators to treat patients under Edison's Expanded Access Investigational New Drug (IND) application 107,401. Enrollment had been restricted to use in subjects with genetically confirmed inherited respiratory chain diseases of the mitochondria. The modified expanded access protocol now includes patients that meet predetermined clinical criteria for mitochondrial disease and where a discrete genetic defect is not identifiable.

Edison CEO Dr. Guy Miller says, "This is a first step in providing patients clinically diagnosed with mitochondrial disease, absent genetically confirmed etiology, broader access to EPI-743. We are grateful to the US and European EPI-743 Investigator Team for their hard work, dedication and commitment."

A first report on EPI-743 data obtained under the Expanded Access IND will be presented at the United Mitochondrial Disease Foundation's scientific meeting this month in Chicago in a session chaired by principal investigator Gregory M. Enns, MB, ChB (Lucile Packard Children's Hospital, Stanford University Medical Center) and Bruce H. Cohen, MD, FAAN (Akron Children's Hospital). A separate abstract was recently presented on EPI-743 and Leber's hereditary optic neuropathy at the American Ophthalmology Society Meeting in May of this year.

MitoAction would like to applaud the worldwide EPI-743 Investigator Team and the vision of Edison Pharmaceuticals on behalf of our children, their families, and the adult mitochondrial patient community. We offer our support and appreciation of their work to develop life-changing treatments for mitochondrial disease.

For more information, please visit www.MitoAction.org/EPI743.