

Remedy Pharmaceuticals' CIRARA Granted Orphan Drug Designation For Treatment of Severe Cerebral Edema Caused By Acute Ischemic Stroke

NEW YORK, New York, January 17, 2017 — Remedy Pharmaceuticals, a privately-held pharmaceutical company focused on bringing life-saving hospital-based treatments to people affected by central nervous system related edema, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for its investigational drug, CIRARA, for treatment of severe cerebral edema in patients with acute ischemic stroke.

“The Orphan Drug Designation, in addition to our FDA Fast Track status, is an important achievement as we advance our development plans for CIRARA to combat severe cerebral edema in large hemispheric infarction,” notes Sven Jacobson, CEO of Remedy Pharmaceuticals. “CIRARA could significantly enhance currently available treatment options for this desperately at-need patient population.”

ABOUT ORPHAN DRUG DESIGNATION

The Orphan Drug Designation Program is administered by the FDA's Office of Orphan Products Development, which grants orphan status to drugs which are intended to treat rare diseases that affect fewer than 200,000 people in the U.S., or diseases that affect more than 200,000 people in the U.S. in circumstances where there is not expectation of recovering the costs of developing and marketing a therapeutic drug.

ABOUT CIRARA

CIRARA is a patented, high affinity inhibitor of Sur1-Trpm4 channels, which are upregulated following ischemia and trauma. Opening of these channels can lead to severe edema, midline shift, increased intracranial pressure and brain herniation, culminating in permanent disability or death. Sur1-Trpm4 channels were discovered by University of Maryland neurosurgeon Dr. J. Marc Simard, scientific founder and board member of Remedy Pharmaceuticals. CIRARA is an investigational drug and is not approved by FDA.

ABOUT REMEDY PHARMACEUTICALS

Remedy Pharmaceuticals, Inc. is a privately-held, clinical stage pharmaceutical company focused on developing and bringing lifesaving treatments to people affected by acute central nervous system (CNS) edema.

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