

## Executive Summary: rhMFG-E8 for Ischemic Acute Kidney Injury (AKI)



**Company Profile:** TheraSource LLC is an early-stage biotech company located in Greater New York City Area, currently employing 9 scientists, mostly with MD or PhD degrees. Our mission is to develop and commercialize protein and peptide-based therapeutics for human inflammatory diseases. The company has 14 utility patents covering 5 molecules.

**Product Description - Recombinant Human MFG-E8 (rhMFG-E8):** Milk fat globule-epidermal growth factor-factor VIII (MFG-E8) is a secretory protein produced in the human body. TheraSource R&D team has discovered that MFG-E8 has excellent anti-inflammatory properties by enhancing the clearance of dying cells, providing protection for the kidneys from ischemic injury.

**Unmet Medical Need in Acute Kidney Injury (AKI):** Ischemic AKI occurs when there is insufficient blood flow to provide oxygen and nutrients to the kidneys. It is frequently observed after major surgical procedures such as cardiac surgery. Occurrence of ischemic AKI is associated with high mortality. No FDA-approved drugs are available to prevent or treat patients with ischemic AKI in the market.

**Value Proposition:** rhMFG-E8 will be administered as a single intravenous injection or continuous infusion after cardiac surgery to prevent or treat ischemic AKI. The success of rhMFG-E8 treatment will benefit patients, shorten hospital stay, and reduce overall healthcare cost.

**Market Opportunity:** More than 395,000 patients undergo cardiac surgery each year in US and 30% of them develop various degrees of ischemic AKI. The market of AKI therapeutics reached \$955 MM in 2009 and has been estimated to be \$1.4 billion in 2014.

**Market Entry Strategy:** TheraSource has developed the technology to produce rhMFG-E8 and multiple assays to monitor its bioactivity and stability. The efficacy of rhMFG-E8 in the treatment of ischemic AKI has been demonstrated in an animal model and published in a peer-reviewed journal. Our patent on the use of rhMFG-E8 for AKI has been issued in European Union (pending in other countries including the US). We are currently preparing for IND-enabling studies and plan to file an IND within 18 months.

**Leadership Team:** Ping Wang, MD, Founder and President, >25-year experience in critical care-related research; well-funded by NIH since 1995; president-elect of the Shock Society; council member of the Surgical Infection Society. Weng-Lang Yang, PhD, CSO, extensive knowledge in protein chemistry, biochemistry, cellular, and molecular biology; experience in drug discovery and pre-clinical development.

**Operations:** We are in the process of contracting CROs for manufacturing, analytical testing, PK/PD, toxicity and immunogenicity testing of rhMFG-E8.

**Financial Position:** TheraSource has raised more than \$12 million from industry and government with 14 SBIR awards from the NIH. We have secured sufficient funding for the next 18 months of operation.

**Objective:** TheraSource seeks strategic VC funding and pharma partners to co-develop and commercialize rhMFG-E8 for ischemic AKI as well as the clinical development of this biologic for other human disease indications.

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