Executive Summary: rhMFG-E8 for Inflammatory Bowel Disease

Company Profile (www.therasourcellc.com):
TheraSource LLC is a growing start-up biotech company located in Long Island, New York. The company currently employs 13 people, mostly with MD or PhD degrees. Our mission is to discover and develop protein/peptide-based therapeutic agents to treat human inflammatory diseases such as sepsis, hemorrhagic shock, acute radiation syndrome, ischemic organ injury, acute ischemic stroke, and inflammatory bowel disease. Since its founding, TheraSource has raised more than $10 million from industry and government entities. We possess 5 patented molecules with 10 utility patents.

Description of MFG-E8:
Milk fat globule epidermal growth factor-factor VIII (MFG-E8) or lactadherin is a protein produced in the human body and abundant in breast milk. TheraSource R&D team discovered that MFG-E8 has anti-inflammatory activity related to an increased clearance of dead cells, reduced inflammatory signaling by immune cells, decreased accumulation of tissue-damaging neutrophils, and maintenance of epithelial integrity in the intestine.

Stage of Development:
TheraSource has developed the technology to produce recombinant human protein (rhMFG-E8) with high purity, none to low toxicity and stability at 4°C through a microbial expression system. With 18 preclinical studies published by TheraSource scientists showing efficacy of MFG-E8, we conclude that rhMFG-E8 has therapeutic potential to treat human diseases. We have also developed several biological activity assays to monitor the quality of rhMFG-E8 product, including phagocytosis of apoptotic cells, inhibition of TNF-α release, cell adhesion, and binding to phosphatidylserine. Currently, we are working with a CMO company to scale-up the production of cGMP-grade rhMFG-E8.

Patents:

Partnering:
TheraSource seeks strategic partnerships with pharma, biotech, and venture capital to co-develop rhMFG-E8 and advance it to clinical stage. We also welcome the opportunity to sell or license our technologies.

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Therapeutic Indication: Inflammatory Bowel Disease
Inflammatory bowel disease (IBD) is characterized by chronic and recurring inflammation and activation of the immune response in the gastrointestinal tract. The two most common forms of IBD are ulcerative colitis (UC) and Crohn’s disease (CD). IBD patients often experience intestinal bleeding, obstruction, and fistula formation, and up to 75% of patients with CD and 25% of those with UC will eventually require surgery. IBD affects 1.4 million persons in the US, and the incidence rates for CD and UC have
increased to 19.2 and 20.2 per 100,000 persons per year, respectively. As such, IBD now accounts for more than 700,000 physician visits, 100,000 hospitalizations, and 119,000 disability cases each year, and its annual health care costs are expected to increase from $1.7 billion in 2011 to $3.2 billion by 2017. IBD has no cure and generally requires lifelong medical care. Conventional and more recently developed biological therapeutic agents have limited efficacy. Therefore, there is a pressing need to develop better therapeutic agents to control IBD and induce lasting, deep remission.

Preclinical studies:

rhMFG-E8 prevents weight loss in experimental IBD. Treatment with rhMFG-E8 significantly decreased weight-loss associated with (A) DSS- and (B) TNBS-induced colitis, two well-established experimental models of IBD. Vehicle (normal saline) or rhMFG-E8 (60 or 120 µg per kg of body weight) was administered daily subcutaneously starting at day 2 in the DSS model and at day 1 in the TNBS model. Data are presented as mean ± SE (n=5/group) and compared using one-way ANOVA with the Student-Newman-Keuls test; *P < 0.05 vs. vehicle.

Publications: