Inflammatory Response Research, Inc.

Innovation through Understanding

Background: Inflammatory Response Research, Inc. ("IRR") is a drug development company focused on pharmaceutical products for the treatment of inflammatory disorders and conditions. Our initial product is a combination of levocetirizine (Xyzal®) and montelukast (Singulair®) at specific dosing for the treatment of the common cold as a 'Behind the Counter' dose pack. In parallel development with Leidos, a major government CRO in Reston, Va., are injectables for use in traumatic brain injury and acute radiation syndrome.

Company Focus: Treatment of inflammatory disorders and conditions, including the common cold, traumatic brain injury, and acute radiation syndrome.

Products in Development: The combination of levocetirizine (Xyzal®) and montelukast (Singulair®)

Levocetirizine, marketed commercially as Xyzal® in the United States by Sanofi-Aventis and UCB, is indicated, among other things, for the relief of symptoms associated with seasonal and perennial allergic rhinitis. Levocetirizine is the most effective antihistamine on the market based on safety and efficacy.

Montelukast, marketed commercially as Singulair® in the United States by Merck, is approved for the treatment of asthma, exercised induced asthma, and the relief of symptoms of seasonal and perennial allergic rhinitis.

Clinical data to date generated by Dr. May, supported by independent laboratory research, suggests the combination of levocetirizine and montelukast shortens the traditional 7-10 day course of common cold by 50%. Both compounds have excellent safety profiles.

Markets: 1) The Common Cold 2) Traumatic Brain Injury 3) Acute Radiation Syndrome

The Common Cold - The number of cold treatment eligible patients is expected to grow to about 170 million by 2020 (Mirubi Group 2012). Currently there is no FDA approved product that actually shortens the duration of the common cold.

Traumatic Brain Injury – TBI is the #1 military medical unmet need with a cost to society at an estimated $80 billion / year. Presently there is no safe and effective pharmacotherapeutic agent to actively treat inflammation following TBI.

Acute Radiation Syndrome – current therapy for the treatment of acute radiation syndrome is primarily supportive: IV fluids, prophylactic antibiotics, ACE inhibitors for pulmonary fibrosis, and bone marrow transplantation.

Regulatory Pathway: Based on preliminary guidance from independent regulatory consultants, IRR believes that the drug combination of levocetirizine (Xyzal®) and montelukast (Singulair®) can proceed directly to a Phase II 'challenge' trial, for treatment of the 'Common Cold' with minimal preclinical study.

Financials: The Company has successfully raised seed capital and is seeking to partner through equity and grant funding. Proceeds will enable IRR to develop the remarkable array of indications including a Phase II clinical trial in the US / Australia.

Contact:

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■ LEADERSHIP:

B. Chandler May, MD, JD, MS, FCLM
President & CEO
B. Chandler May, MD, JD, MS, FCLM is a physician-attorney in private practice in Santa Barbara, California. His clinical practice / research encompasses more than thirty years of experience in general otolaryngology, with an emphasis on respiratory medicine, trauma, and infectious disease.

Loriel May, CFO
Twenty-eight years of accounting and finance experience

William Pedranti, JD.
Adviser / Chief Operating Officer of SCILEX

Mark Benedict, JD, Ph.D., Partner
IP Counsel – Knobbe Martens:
'Fifty years, one focus'

Jonathan Gilthorpe, PhD., Sweden
21 years of research experience in Neurobiology, Neurodegeneration and Infection Biology

■ COMPANY STATUS

California corporation established: 2011

■ INTELLECTUAL PROPERTY

PCT Int. Application filed Dec 2012, priority to US Provisional Appl. filed Jun 16, 2010

2013-2016 - additional IP filed addressing multiple indications

2015 - initial patent issued in the US, Australia, Mexico, and Japan

2016 – initial patent issued in Canada
2016 – patent for TBI issued in the US

2017 – patent for autoimmune disorders and vasculitis issued in the US
2017 – notice of allowance for TBI in Europe

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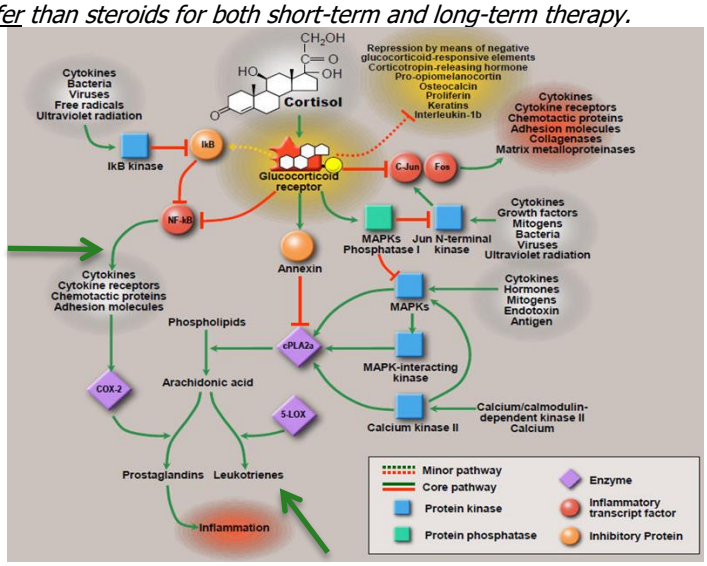
Scientific Rationale: A detailed examination of the pharmacokinetics of levocetirizine at the cell level illuminates the unique anti-inflammatory properties that extend beyond the IgE mediated release of histamine. Most important are its low volume of distribution (0.4 L/kg; ideal drug ≤ 0.6 L/kg), prolonged dissolution time from the H1 receptor in an acidic ph, enhanced receptor affinity as the pure isomer of cetirizine, fastest onset (0.9 hour), fastest to steady state, (approximately 40 hours), and the highest receptor occupancy at 24 hours of any currently available antihistamine. Such parameters impart an anti-inflammatory effect by down regulating the signaling proteins: IL-4, IL-6, and IL-8 as well as cellular adhesion molecules. The latter are a homogeneous group of inducible immunoglobulins, integrins and selectins involved in cell-to-cell adhesion, cellular recruitment, homing and healing.

Levocetirizine has been shown in a laboratory model to decrease ICAM-1, IL-6, IL-8, TLR3 expression and NF-kappa B activation resulting in decreased human rhinovirus (HRV) titers by log-2. Levocetirizine inhibits rhinovirus-induced ICAM-1 and cytokine expression and viral replication in airway epithelial cells. Separate research has shown that many rhinovirus serotypes share the same cellular receptor identifying ICAM-1 as the portal of entry into the cell. Independently, a one-log reduction in viral shedding results in a significant clinical benefit in HRV-infected patients.

Montelukast acts at the CysLT1 receptor to inhibit the physiologic action of leukotriene D4 (LTD4). Leukotrienes are protein mediators of inflammation similar to histamine; however 100-1000x more potent than histamine in the lung. LTD4 is the most potent cysteinyl leukotriene in contracting smooth muscle, thereby producing bronchoconstriction. Moreover, both montelukast and levocetirizine are known to reduce the quantity of eosinophils or their migration to the site of inflammation. An eosinophilic infiltrate is considered a "hallmark" of inflammation.

As depicted below, the two molecules act synergistically in separate arms of the steroid pathway to block inflammation; however, are significantly safer than steroids for both short-term and long-term therapy.

levocetirizine



montelukast

Figure 1. Adapted by permission: Rhen T, Cidlowski JA. Anti-inflammatory Action of Glucocorticoids - New Mechanisms for Old Drugs. N Engl J Med 2005

Acting at multiple points within both the innate and adaptive portions of the immune system, injectables capable of sustaining constant tissue levels will be ideal as 'First Response' medications for the treatment of traumatic brain injury (TBI) and acute radiation syndrome (ARS).

Intellectual Property Update: 8 Issued Patents / 48 Pending Worldwide

Our initial use patent for influenza and the common cold issued in the United States, June 2015. The initial patent has issued as well in Australia, Japan, Canada and Mexico. Levocetirizine + montelukast for the treatment of traumatic brain injury (TBI) issued in the United States, December 2016 with notice of allowance for TBI in Europe, June 2017. Separate yet closely related research underscored a sixth filing in September 2015 for the treatment of progressive neurological disorders through a common immunologic pathway – NF-kB. Supporting animal research was independently presented in Chicago at the Society for Neuroscience, October 2015. https://www.newscientist.com/article/dn28384-old-rat-brains-rejuvenated-and-new-neurons-grown-by-asthma-drug/

Thank you for your interest in IRR, Inc.

B. Chandler May, MD, JD, MS, FCLM