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OrPro Therapeutics Receives US Patent Covering Novel Enzymatic Treatment for Cystic Fibrosis

- Broad claims extend protection to 2034 -

- in vivo safety and mechanism-based proof of concept data presented at key conferences -

SAN DIEGO, October 27, 2015 -- OrPro Therapeutics, Inc. announced today that the US Patent and Trademark Office (USPTO) has issued U.S. Patent No. 9,168,290 covering the ability of Theradux™ (recombinant modified human thioredoxin-1) to improve the viscoelastic properties of mucus secretions in patients with diseases characterized by excessively viscous or cohesive mucus or sputum, such as cystic fibrosis (CF) and other obstructive lung diseases.

In CF patients, mucus is unable to perform its essential function of clearing the lungs, leading to life-threatening chronic infection and inflammation. Theradux is an inhaled, non-systemic version of the naturally-secreted enzyme thioredoxin which helps to prevent excess molecular bonds from forming within the mucus layer. The demonstrated deficiency of this activity in patients with CF may be a key driver for progressive impairment of lung function. Treatment with nebulized Theradux, which relaxes abnormally stiffened mucus, is anticipated to help restore mucus transport and clearance in the majority of CF patients. Theradux is expected to work both alone and in concert with approved and in-development Cystic Fibrosis Transmembrane Regulator (CFTR) modifier therapies to further slow the progression to lung failure, a critical unmet need in CF.

The broad claims issued today are the first in a new US and international patent family owned by OrPro that extends coverage to at least 2034 and adds to the company’s existing in-licensed patent estate surrounding thioredoxin’s ability to modify the viscoelasticity of mucus. OrPro is the exclusive licensee of issued and pending thioredoxin-related patents from its research partner National Jewish Health (Denver, CO), the leading US respiratory hospital.

“The wide scope of this patent reflects the novelty of our research findings and their importance in creating new treatment options for patients in need” said Peter B. Heifetz, Ph.D., president and CEO of OrPro.
At the recent 2015 North American Cystic Fibrosis Foundation Conference, OrPro presented results from in-vitro and in-vivo studies of Theradux funded by the National Heart, Lung and Blood Institute of the National Institutes of Health (NIH/NHLBI) and the Cystic Fibrosis Foundation. This work confirmed the unique mucus-binding mechanism of Theradux and demonstrated a lack of toxicity and inflammation in pre-clinical, acute aerosol-inhalation studies. OrPro will also present these data at the upcoming NIH/NHLBI Innovation Conference – West on November 17, 2015 in Irvine, CA.

About Cystic Fibrosis

CF is characterized by overproduction of thickened mucus resulting in impaired lung function, chronic infection and premature death and is the most common inherited lethal disease among populations of primarily Northern European descent. CF affects more than 30,000 individuals in the United States and nearly 80,000 worldwide. While the life expectancy of CF patients has continued to increase, from 18 years prior to 1980 to nearly 40 years today, there is still an urgent need for improved therapies to further extend life expectancy and enhance quality of life.

About OrPro

OrPro Therapeutics, Inc. (San Diego, CA) is developing a therapeutic platform based on thioredoxin, a human protein disulfide-reducing enzyme with unique mucus-normalizing, anti-inflammatory and anti-infective properties. OrPro’s lead candidate Theradux (ORP-100) is a new inhaled treatment designed to treat cystic fibrosis (CF) and other obstructive diseases characterized by thickened, stiff and adhesive mucus. The company’s research facilities are located on the Torrey Pines mesa at the 40,000 square foot JLABS facility at Janssen Research & Development’s La Jolla-based West Coast Research Center. JLABS is a "no strings attached" model that provides core research labs hosting specialized capital equipment, shared administrative areas and individual bench, wet lab and office modules.

Contact:

Jeff Raser
OrPro Therapeutics, Inc.
(858) 242-1557
jraser@orprotherapeutics.com

Michele Parisi
FHC, Inc.
(925) 429-1850
mparisi@biocommnetwork.com