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FOR IMMEDIATE RELEASE

Study Shows Need to Test More COPD and Asthma Patients for Underdiagnosed Pulmonary Disease

On World COPD Day, Physicians Urged to Use Wider Screening Criteria for Alpha-1 Antitrypsin Deficiency

KING OF PRUSSIA, PA, November 14, 2007 – A new study finds that a higher than expected number of COPD and severe asthma patients had abnormal low levels of alpha-1 antitrypsin (AAT), suggesting that need for broader criteria for AAT deficiency testing. AAT deficiency, also known as Alpha-1, is a widely undiagnosed hereditary disorder that is usually fatal in its severe form.

Alpha-1 is estimated to affect up to 100,000 Americans, but up to 95 percent are undiagnosed or have been misdiagnosed as having another form of chronic obstructive pulmonary disorder (COPD). Details of the study were presented at CHEST, the annual meeting of the American College of Chest Physicians held in Chicago from October 20 to 25. Study results are being announced today on World COPD Day to focus attention on the need for wider testing for AAT deficiency.

“Findings from this study suggest that simply all patients with moderate or severe persistent asthma and/or COPD with chronic pulmonary symptoms should be tested for AAT deficiency,” said Gary Rachelefsky, MD, Professor of Allergy and Immunology and Director of the Executive Care Center for Asthma, Allergy and Respiratory Diseases at UCLA School of Medicine and study investigator. “It is imperative that clinicians become more vigilant about Alpha-1 testing as many patients are going undiagnosed or misdiagnosed due to screening criteria and practices.”

The study, conducted by the Respiratory & Allergic Disease Foundation, recruited 40 office-based pulmonologists across the United States who tested 454 adult patients using the following simple

screening criteria: persistent asthma and/or COPD patients with loss of lung function defined by either a FEV₁ (forced expiratory volume at 1 second) or a ratio of FEV₁ to forced vital capacity (FEV₁/FVC) of less than 70 percent. Blood tests were taken to assess levels of AAT, and additional lab results and patient histories were noted and tabulated.

Of the 454 patients studied, 3.3 percent showed deficient levels of AAT. Low blood levels of AAT are commonly associated with progressive severe emphysema that becomes clinically evident by the third to fourth decade of life; a recent registry showed that 54 percent of AAT deficient patients had emphysema. Less commonly, low levels of AAT are associated with liver disease and cirrhosis.

Interestingly, patients who tested with low AAT did not significantly differ from the COPD/persistent asthma patients with normal levels of AAT in several key pulmonary function criteria, including levels of FEV₁, ratios of FEV₁ to forced vital capacity (FEV₁/FVC), or the number of bronchial infections within the past 12 months. This lack of differentiating characteristics in deficient subjects indicates that if pulmonologists rely on standard screening criteria for Alpha-1 testing, the result will be incorrect and missed diagnoses.

“Our surveillance study found that physicians cannot depend on typical patient profiles to assess whether AAT deficiency screening is necessary. There is no ‘face’ to AAT deficiency,” said D. Kyle Hogarth, MD, FCCP, Assistant Professor of Medicine, University Chicago Medical Center, Director of the Alpha-1 Antitrypsin Deficiency Clinical Resource Center at the University of Chicago and lead author of the study. “A number of patients who would not normally be screened based on suggested guidelines turned out in fact to be positive for AAT deficiency. In the real-world setting, this suggests that thousands of patients who have been diagnosed with COPD or severe asthma may actually have Alpha-1.”

The RAD study was supported by an unrestricted educational grant from CSL Behring, maker of the Alpha₁ Proteinase Inhibitor (Human), Zemaira[®].

About Alpha-1 Antitrypsin Deficiency (Alpha-1)

Alpha-1 antitrypsin is an anti-inflammatory protein that protects the tissue of the body. One of its most important roles is to shield the delicate tissues of the lungs by binding to neutrophil elastase, an enzyme released by certain white blood cells that digests bacteria and other foreign substances in the lungs. When a person with deficient levels of AAT inhales irritants or contracts a lung infection, the neutrophil elastase released to protect the lungs is uncontrolled and can injure healthy lung tissue. Repeated injury to the normal structure of the lungs can eventually result in emphysema, a condition affecting 54 percent of diagnosed AAT deficient patients, according to a recent registry. Identifying patients with AAT deficiency can be problematic, however. Because AAT deficiency typically involves such common symptoms as shortness of breath on exertion, wheezing, and coughing, the condition is often misdiagnosed as another chronic lung condition. In fact, retrospective studies show that even after an Alpha-1 patient has developed symptoms, it can take an average of seven years and visits to five different healthcare professionals before the correct diagnosis is made. Researchers estimate that up to 100,000 adults and children in the U.S. have severe Alpha-1, and 25 million people nationwide may be carriers. Only about 5,000 patients are currently diagnosed as AAT deficient, meaning that up to 95 percent of people with the deficiency remain undiagnosed.

CSL Behring to Launch National Campaign to Improve Detection of AAT Deficiency

To advance the early diagnosis and treatment of AAT deficiency, CSL Behring, a leader in alpha-1 research and treatment, is launching a national education and support program called *Test Today. Change Tomorrow*. The initiative will target patients, caregivers and healthcare professionals with activities and services, such as a national disease awareness campaign about Alpha-1 deficiency, a toll-free information center and website, educational materials, and a program to support Alpha-1 testing in healthcare settings, called Champions for Alpha-1 Testing. *Test Today. Change Tomorrow*. will begin the week of November 18 with the launch of a national television show as part of the series *Today's Health*. For more information, call CSL Behring Consumer Affairs at 1-866-936-2472, or visit www.testtodaychangetomorrow.com.

CSL Behring is the maker of Alpha₁-Proteinase Inhibitor (Human), Zemaira[®], which is indicated for chronic augmentation and maintenance therapy for individuals with established AAT deficiency and clinical evidence of emphysema. Zemaira[®] is not indicated as therapy for lung disease patients in whom severe congenital A₁-PI deficiency has not been established. Clinical data demonstrating the long-term effects of chronic augmentation therapy with Zemaira are not available.

As with other Alpha-1 therapies, Zemaira may not be appropriate for the following adult individuals as they may experience severe reactions, including anaphylaxis: individuals with a known hypersensitivity and/or history of anaphylaxis or severe systemic reaction to Alpha-1 Proteinase Inhibitor products or their components and individuals with selective IgA deficiencies who have known antibodies against IgA.

In clinical studies, the following treatment-related adverse reactions were reported in 1 percent of subjects: asthenia (fatigue), injection-site pain, dizziness, headache, paresthesia (tingling) and pruritus (itching).

Zemaira is derived from human plasma. As with all plasma-derived products, the risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent, cannot be completely eliminated.

About CSL Behring

CSL Behring is a global leader in the plasma protein biotherapeutics industry. Passionate about improving the quality of patients' lives, CSL Behring manufactures and markets a range of safe and effective plasma-derived and recombinant products and related services. The company's therapies are used in the treatment of immune deficiency disorders, hemophilia, von Willebrand disease, other bleeding disorders and inherited emphysema. Other products are used for the prevention of hemolytic diseases in the newborn, in cardiac surgery, organ transplantation and in the treatment of burns. The company also operates one of the world's largest plasma collection networks, ZLB Plasma. CSL Behring is a subsidiary of CSL Limited, a biopharmaceutical company with headquarters in Melbourne, Australia. For more information, visit www.cslobehring.com.

About the Respiratory & Allergic Disease Foundation

The Respiratory & Allergic Disease Foundation (RAD) is a physician-led 501(c)(3) non-profit corporation that provides education for patients and clinicians on allergic and respiratory diseases that affect millions of people in the United States. As new approaches evolve for the treatment of respiratory and allergic diseases, RAD is committed to developing scientific and educational programs for healthcare professionals that incorporate the latest developments in understanding and treating these conditions.

With the assistance of our world-class steering committee, network of faculty and participants across the United States, RAD provides healthcare professionals with the cutting-edge, practical education needed to move respiratory medicine forward. Learn more at www.rad-foundation.org.