Inner-City Children with Asthma to Test Advanced Medication

Researchers will test antibody already approved for treatment in adults and adolescents

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DENVER — Scientists at the National Jewish Medical and Research Center, Denver Health Medical Center and other academic medical centers recently launched a major study to evaluate whether a medication approved for adolescents and adults can help to reduce the severity of allergy symptoms and asthma attacks in inner-city children.

Dr. Andrew Liu, Associate Professor and his team of clinical researchers will carry out the "Inner-City Anti-IgE Therapy for Asthma" (ICATA) study as a research site for the Inner City Asthma Consortium (ICAC), a federally-sponsored, $55.8 million, six-year contract awarded to and administered by the University of Wisconsin-Madison.

ICAC was formed to identify the causes of, and best treatments for, asthma in urban children, a significant and growing national health problem.

"Children who have allergies are at greater risk for developing asthma than those who do not," says Dr.Liu. "Allergens such as house dust mites, cockroaches, molds and animal dander that trigger allergic reactions may contribute to the severity of the child's asthma."

Avoiding allergens is difficult and not always effective, Dr. Liu adds.

"Making matters worse is the fact that children living in America's inner cities are exposed to higher allergen levels and tend to have more acute asthma than those living elsewhere," he says.

The current standard treatments for asthma are generally effective, but must be used on a daily basis. Still, children can have an asthma attack despite good medical care and regular medication use, Dr.Liu says.

"Caring for inner city children is complicated by factors such as infrequent visits to primary care clinics, poor adherence to prescribed medication schedules, basic misconceptions about the nature of asthma, and the impact of living in an urban environment that presents multiple, ongoing allergic triggers," says Dr. Liu.

Researchers will evaluate Xolair® (omalizumab) for subcutaneous use, a medication that is already approved for use in adolescents and adults, to determine if adding it to existing treatments improves outcomes for urban children with asthma. Xolair is a humanized monoclonal antibody that binds to, and inactivates, IgE antibodies. IgE antibodies are the immune system drivers of allergic reactions.

"IgE is produced when the body is exposed to allergens, sometimes resulting in allergic asthma," notes Dr. Liu. "We already know that Xolair injections can lower the frequency of asthma exacerbations and reduce asthma symptoms in patients with moderate to severe persistent allergic asthma, but we need to see if, and how, it works in an urban environment."

Xolair is administered via subcutaneous injection every two or four weeks compared to other asthma medications that are used every day. Xolair can provide long-lasting effects and directly blocks the cause of allergic reactions, which produce the most common form of asthma.

"Xolair may be a very beneficial treatment for allergic asthma in patients for whom allergic factors such as house dust mites or cockroaches are difficult to control or avoid," Dr. Liu says.

The ICATA-study will use an initial blinded, controlled-trial format and then all participants will receive the Xolair medication in an open-label fashion. All participants will benefit from nearly two years of care provided at the ICAC research sites (see list below). Extensive laboratory analyses of biological and environmental samples collected over the course of the study will occur.

The total cost of the study, excluding nearly $6 million of study medication which will be provided at no cost by Novartis Pharmaceuticals Corporation and Genentech Inc., is expected to exceed $15 million. Novartis Pharmaceuticals Corporation and Genentech Inc. will also supply $8 million of the total budget, and the balance will be provided by the National Institute of Allergy and Infectious Diseases, which funds the ICAC contract.

The ICAC clinical research sites, statistical and clinical coordinating center (SACCC) and administrative center include: University of Arizona, Tucson; Boston University, Boston; Children's Memorial Hospital, Chicago; Rainbow Babies and Children's Hospital, Cleveland; Children's National Medical Center, Washington, D.C.; University of Texas Southwestern Medical Center, Dallas; National Jewish Medical and Research Center, Denver; Johns Hopkins University, Baltimore; Mount Sinai School of Medicine, New York; St. Louis Children's Hospital St. Louis; Rho Federal Systems Division, Inc., Chapel Hill, N.C. (SACCC) and UW-Madison, (administrative center).

For more information please contact Julie Henley, Lead Coordinator for this study, at National Jewish Medical and Research Center at **303-398-1608**.

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