Ann & Robert H. Lurie
Children's Hospital of Chicago®

The FARE Clinical Network & New Research Studies

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BEST CHILDREN'S HOSPITALS
U.S.News & WORLD REPORT
HONOR ROLL 2015-16

2013 Parents 10 BEST CHILDREN'S HOSPITALS

MAGNET RECOGNIZED
AMERICAN NURSES CREDENTIALING CENTER

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Changing the Face of Food Allergy Care: FARE Clinical Network

The FARE Clinical Network (FCN)

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- Created by FARE in 2015
  - A nationwide network of 24 leading research and clinical care facilities, the FARE Clinical Network brings members together for a common goal of ensuring that patients with food allergies have access to:
    - State-of-the-art diagnosis,
    - Treatments, and
    - Research.
  - The FARE Clinical Network is a powerful driver of collaboration to advance the field of food allergy.
    - Aims to accelerate the development of drugs for patients with food allergies.
    - Aims to improve the quality of care for this serious illness.
    - FARE hopes to add 3 –4 additional FCN sites in 2016, with the long-term goal of 40 –50 sites.

The FARE Clinical Network (FCN)

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- Creation of Research Sites that are "Centers of Excellence"
  - Under FARE's leadership and coordination, the centers selected to participate in this nationwide network:
    - Serve as **Centers of Excellence** that:
      - Develop best practices for the care of patients with food allergies, and
      - Serve as sites for clinical trials for the development of new therapeutics, and
      - Contribute to the development of a national food allergy patient registry and biorepositories.
- Lurie Children's Hospital is a part of the FCN:
  - Recognized in June 2015
  - FARE funded Clinical Research Coordinator hired in October 2015
  - 3 pivotal clinical trials started in first quarter 2016

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Pepites

Lurie Children's: New Research Studies

Palisade
TRIAL

New Research Studies: MILES

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- A DOUBLE-BLIND, PLACEBO-CONTROLLED RANDOMIZED TRIAL TO STUDY THE VIASKIN MILK EFFICACY AND SAFETY FOR TREATING IgE-MEDIATED COW'S MILK ALLERGY IN CHILDREN
  - Study Sponsor: DBV Technologies
    - Phase 1/2 study
      - Investigational Product: Viaskin Milk patch applied to the skin.
      - ~194 subjects will be randomized to 3 different Viaskin Milk patch doses (150µg/ 300µg/ 500µg of cow's milk protein) vs. placebo patch - (Ratio 1:1:1:1).
- Primary Objectives
  - To evaluate the safety and efficacy of Viaskin Milk to induce desensitization to cow's milk after 12 months of EPIT treatment.

(EPIT = EPicutaneous ImmunoTherapy)

New Research Studies: MILES

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- Sites
  - ~18 sites in US/Canada
  - Lurie Children's enrollment goal is 12 patients; ages 2 -17 years old.

- Enrollment Milestones at Lurie Children's:
  - First patient screened in February 2016
  - First patient enrolled in March 2016
  - Last patient enrolled ~ May/Jun-2016

- Study Timelines
  - Last Patient, Last Visit – June 2017

New Research Studies: PEPITES

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- A DOUBLE-BLIND, PLACEBO-CONTROLLED, RANDOMIZED PHASE III PIVOTAL TRIAL TO ASSESS THE EFFICACY AND SAFETY OF PEANUT EPICUTANEOUS IMMUNOTHERAPY WITH VIASKIN PEANUT IN PEANUT-ALLERGIC CHILDREN
  - Study Sponsor: DBV Technologies
    - Phase 3, pivotal study
      - Investigational Product: Viaskin Peanut patch applied to the skin.
      - 330 subjects will be stratified at randomization by their DBPCFC entry/screening ED (entry peanut eliciting dose) in 1 of the 2 strata:
        - Stratum 1: children with a screening ED of 1 mg, 3 mg or 10 mg.
        - Stratum 2: children with a screening ED of 30 mg, 100 mg or 300 mg.
        - The randomization scheme will ensure that the ratio of active treatment to placebo is maintained in each stratum.

New Research Studies: PEPITES

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- Primary Objectives
  - To assess the efficacy and safety of Viaskin Peanut to desensitize peanut-allergic children after a 12-month EPIT treatment.
- Sites
  - This is a multicenter study to be conducted in Australia, Europe and North America. It is planned that approximately 28 to 40 sites from 4 to 7 countries will participate.
  - Lurie Children's enrollment goal is 15 patients; ages 4-11 years old.
- Enrollment Milestones at Lurie Children's:
  - First patient screened – February 2016
  - First patient enrolled – March 2016
  - Last patient enrolled ~ July 2016
- Study Timelines
  - Last Patient, Last Visit ~ July 2017

New Research Studies: PALISADE

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- PEANUT ALLERGY ORAL IMMUNOTHERAPY STUDY OF AR101 FOR DESENSITIZATION IN CHILDREN AND ADULTS
  - Study Sponsor: Aimmune Therapeutics, Inc.
    - Phase 3, pivotal study.
      - Investigational Product: AR101 - a pharmaceutical-grade peanut allergen formulation.
      - 500 peanut-allergic subjects will be randomized 3:1 to peanut oral immunotherapy (OIT) versus placebo.
- Primary Objective
  - The primary objective is to demonstrate the efficacy of AR101 through reduction in clinical reactivity to limited amounts of peanut allergen.
- Secondary Objectives
  - To demonstrate the safety of AR101.
  - To evaluate the immunological effects of peanut OIT therapy.

New Research Studies: PALISADE

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- Sites
  - ~40 sites US/Canada
  - ~15 sites Europe
  - Lurie Children's enrollment goal is 12 patients; ages 4 -24 years old.

- Enrollment Milestones at Lurie Children's:
  - First patient screened – TBD April 2016
  - First patient enrolled – TBA April 2016
  - Last patient enrolled – third quarter 2016

- Study Timelines
  - Last Patient, Last Visit – third quarter 2017

New Research Studies: MILES, PEPITES, & PALISADE

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- There is no guarantee that participation these studies will help the subjects.
- The subjects may receive placebo during the double-blind treatment period of the studies.
- Information from these studies may help researchers to better understand food allergies or to develop tests/treatments to help future patients.
  - For more information email us: allergystudy@luriechildrens.org
  - Check out Clinicaltrials.gov – mandatory list of all FDA clinical trials.
  - Check out our Lurie Children's Division of Allergy and Immunology Research website.

Thank you!

Time for questions…