

FOR IMMEDIATE RELEASE

PuraCap™ Pharmaceutical Reports Key Involvement in Trial of a Ceramide-Dominant Emulsion for the Prevention of Atopic Dermatitis in Newborns

EpiCeram® Skin Barrier Treatment Administered to Babies at High Risk for Eczema

South Plainfield, NJ – February 27, 2014 PuraCap™ Pharmaceutical today announced its supportive participation in the “Prevention of Eczema by a Barrier Equilibrium Strategy” Trial conducted under the sponsorship of the Murdoch Children’s Research Institute and in collaboration with the University of Melbourne and The Royal Women’s Hospital in Melbourne, Australia. The study, known as the PEBBLES Trial, is designed to assess the twice-daily use of EpiCeram® Controlled Release Skin Barrier Emulsion, a ceramide-dominant complete lipid mixture, as a strategy to prevent the development of eczema in infants at increased risk for developing allergic conditions.

It is now recognized that skin barrier function plays a critical role in the development of eczema. Since infants have a poorer skin barrier function than adults, it is possible that defects in barrier function in early life results in increased risk of eczema. The PEBBLES study intends to evaluate this hypothesis with daily intervention of EpiCeram to replenish and improve skin barrier function, thereby reducing the incidence of this very common and painful skin disease.

EpiCeram clinical efficacy and physician experiences will be showcased at two upcoming national scientific meetings: The 2014 American Academy of Allergy Asthma and Immunology on February 28-March 4 in San Diego (Exhibit Booth #108); and the 2014 American Academy of Dermatology on March 21-25 in Denver (Exhibit Booth #1754).

According to specialists, precluding the development of eczema and its first cousin atopic dermatitis may be the first step in the prevention of the "Atopic March," a documented progression of allergic disease manifested first by eczema, followed by food allergy, allergic rhinitis and asthma.

“We have designed this Phase II trial to provide the data necessary to validate that a novel lipid-rich replenishing agent can restore skin barrier function in newborns, and thereby prevent the onset of eczema and progression to other allergic diseases,” said Dr. Adrian J. Lowe, PhD, Murdoch Childrens Research Institute, Parkville, Australia, and lead investigator of the PEBBLES Study. “We are grateful to PuraCap for supplying EpiCeram for this clinical study.”

About the PEBBLES Trial

In the current randomized controlled trial, 100 infants with a first-degree history of allergic disease (eczema, asthma or food allergy) will be recruited. The clinical outcome assessor will be blinded to whether subjects receive product or are in the control group. Evaluations of skin barrier function will take place at 6 weeks, 6 months and 12 months of age. Primary endpoints are the incidence of eczema and allergic sensitization at 6 and 12 months, along with skin barrier function at 6 weeks and 6 months.

The PEBBLES Trial follows an Australian pilot study of 10 at-risk infants from birth to four weeks of age who underwent application of EpiCeram to the full skin surface, excluding hands and face, during a six-week intervention period. Researchers concluded that clinical results support the safety and parental compliance with daily application of this novel approach for the prevention of eczema.

“PuraCap is pleased to provide EpiCeram for this important clinical trial that will further our understanding of atopic dermatitis and potentially influence the incidence of this prevalent childhood disease,” said Elise Klein, VP of Brand Marketing for PuraCap Pharmaceutical. “We are optimistic that early interventions to improve skin barrier will also help reduce the risk of asthma, allergic rhinitis and food sensitivities that impair the quality of life for young children and their families.” The PEBBLES study is funded by the Financial Markets for Children and the Asthma Foundation of Victoria.

EpiCeram Controlled Skin Barrier Emulsion is a controlled-release, prescription product that helps to relieve the burning and itching associated with skin conditions such as atopic dermatitis/eczema. It is the only topical agent formulated with three essential lipids (ceramides, free fatty acids, and cholesterol) in a physiologically balanced ratio, which mimics the lipid concentration found in the skin. A steroid-free topical formulation, EpiCeram is FDA-cleared for the treatment of eczema.

About PuraCap™ Pharmaceutical LLC

PuraCap™ Pharmaceutical LLC is an emerging, fully integrated pharmaceutical company with expertise in product development, manufacturing and bringing affordable, world-class quality products to their customers. The PuraCap™ corporate structure supports their three-prong approach for global growth with dedicated companies in the areas of prescription brands, PuraCap™ Pharmaceutical LLC; prescription generics, PuraCap™ Laboratories Inc.; and OTC and Private Label products, PuraVation™ Pharmaceuticals Inc. For more information on PuraCap™ Pharmaceutical LLC, visit the company’s website at <http://www.PuraCap.com>.

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