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Oral Tolerability of Cysteine-Rich Protein Isolate (Immunocal) in Autism – A Pilot Study

Montreal, Quebec, Canada, August 28, 2008

Immunotec Inc. (TSX-V: IMM) announced today the completion of an open-label clinical trial on the use of a cysteine-rich protein isolate in children with autism. This preliminary study showed the majority of autistic children were easily able to consume non-denatured whey protein isolate (Immunocal®) without adverse effects. The promising results will allow further studies to proceed to demonstrate the benefits of augmented glutathione levels in children with autism. Changes in behavioural aspects were also documented but did not reach statistical significance because of the small number of patients in this pilot study. However, positive trends in all behavioural parameters were noted.

(Kern JK, Grannemann BD, Gutman J, Trivedi MH, *Oral Tolerability of Cysteine-Rich Whey Protein Isolate in Autism – A Pilot Study*, Journal of the American Nutraceutical Association (JANA), Vol. 11, No. 1, 36-41, 2008.)

Recent evidence suggests that many children with autism have low levels of glutathione in their cells. Non-denatured whey protein can improve glutathione levels in a variety of diseases and disorders; however, there are anecdotal reports that children with autism may have problems with ingestion of similar sulfur-rich compounds, e.g., worsening of behavior and/or gastrointestinal (GI) disturbance. This 6-week open-label trial was conducted to examine the feasibility of using whey protein isolate in the treatment of autism. Specifically, the questions addressed were: (1) "Will the children take the supplement?" and (2) "Will the supplement be tolerated?" As a secondary measure, behavioral changes were documented.

Ten children, 3-15 years of age with a diagnosis of autism or autism spectrum disorder (ASD), were supplemented with a non-denatured whey protein isolate (Immunocal®). Autism symptoms, behavior, side effects, and treatment adherence were examined, as well as baseline bowel flora.

Seven out of the ten children took the supplement over the six-week trial and tolerated it well. Two children discontinued after two weeks due to possible side effects although it was not certain that symptoms were due to the Immunocal. One child had mild abdominal discomfort and one seemed less responsive to his parents. Despite the convenient options available to mix the supplement in juice or food, one child discontinued because of difficulty on the parent's behalf in administering the supplement.

Several behavioral parameters were measured including the Childhood Autism Rating Scale (CARS) and the Aberrant Behavior Checklist (ABC) before and after treatment. Results suggest that overall there was no worsening of behavior. Although the small numbers of patients did not allow statistical significance to be attained, all measurements showed a trend toward improvement. Principle investigator Dr. Janet Kern stated, "We're very optimistic about these pilot results, it makes us very comfortable to pursue larger and longer-term studies using this strategy."

Immunotec President and CEO Jim Northrop is pleased with these initial results. "Completion of this pilot study will encourage researchers to move on to the next step of studying the role and benefits of our cysteine-rich protein (Immunocal) in children with autistic spectrum disorder. I am proud of Immunotec's foundational commitment to ongoing research and development that continues to validate the confidence and quality in our products."

About Immunocal

Immunocal is a cysteine-rich protein isolate derived from non-denatured whey protein. Immunocal®/HMS 90®, is a dietary natural health supplement, developed and marketed worldwide by Immunotec since 1996. Immunocal®/HMS 90® is a precursor of the major cellular antioxidant glutathione, an element important in maintaining a strong immune system.

About Immunotec Inc.

Immunotec is engaged primarily in the development and marketing of natural health products, dietary supplements, vitamins and personal care products, many of which are manufactured on its behalf by third parties. Immunotec's products are distributed and sold in the United States and Canada through a network marketing system and in other countries through exclusive distributorship agreements. Immunotec's investment in this study is another manifestation of its ongoing commitment to research and development. www.immunotec.com.

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