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SCIENCE REPORT

Summary of Human Clinical Trials on EpiCor®

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Scientific Affairs

Summary:

Three human clinical trials conducted with EpiCor show its beneficial immune modulating effects.

- ***The first trial studied EpiCor's effect on supporting immune health to reduce cold and flu symptoms in the Midwest during January, February and March. The participants taking EpiCor saw a reduction in the number of days they had colds and flu symptoms by 32% over this period.***
- ***Trial two shows EpiCor increased secretory Immunoglobulin A (sIgA) (the body's first line of defense).***
- ***The third clinical trial examined how EpiCor balances the immune system by increasing sIgA while reducing the increase of serum immunoglobulin E (sIgE) induced by potential appears allergens. This balancing effect appears to be related to reduced allergy symptoms in trial participants taking EpiCor.***

The gold standard for research in the dietary supplement industry is the human clinical trial, and several have been completed with EpiCor. All the trials described below are in various stages of manuscript preparation for submission to peer-reviewed journals. Independent contract research organizations conducted two of the three trials using appropriate and accepted methodology and statistics. The other trial was carried out in-house, again using generally accepted methods.

STUDY OF EPICOR DURING COLD AND FLU SEASON

In the first trial, the clinical benefits of EpiCor were assessed in a large, independently conducted double-blinded placebo-controlled human clinical trial. To do this, 232 people were recruited to study the effects of EpiCor on incidence and severity of potential upper respiratory tract infections (URTI). This large group was chosen to represent the general population aged 18 years and older.

The trial took place during the expected worst cold and flu months – January, February, and March – in South Dakota. Subjects received physical examinations at screening to ensure a healthy study population, and were assigned randomly to receive either EpiCor (500 mg) or placebo. Fasting blood samples were taken at randomization, week six, and at week 12 (when the trial ended). Additionally, each subject was given a diary and

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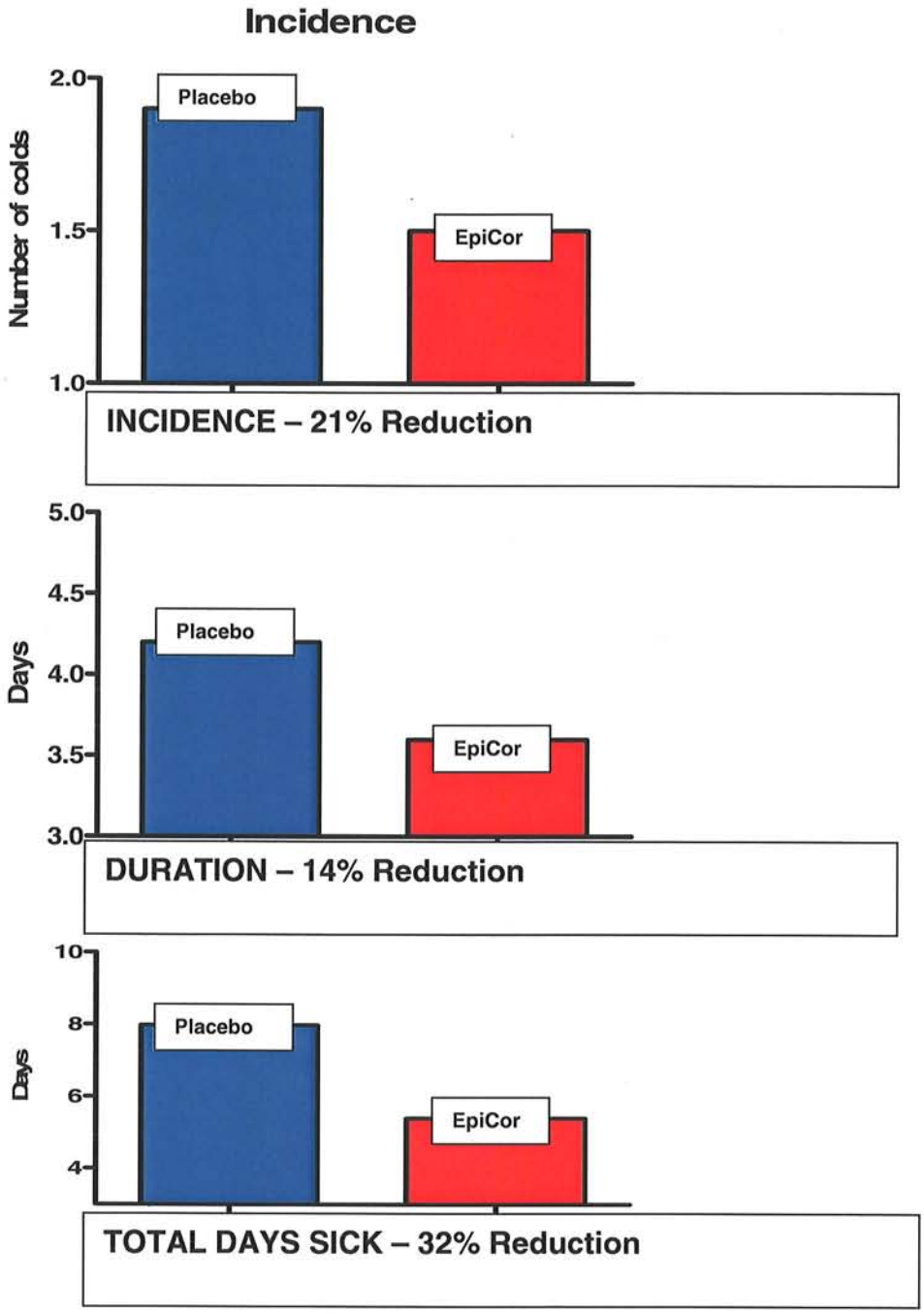
instructed to record duration and severity of cold and flu symptoms.

In subjects taking EpiCor, the incidence of URTIs was statistically significantly reduced. A statistic known as the "p-value" was 0.0000008 – meaning that the probability that the reduction in URTIs in the EpiCor group occurred by chance was less than one in a million. Furthermore, in the rare cases when the EpiCor subjects did get URTIs, the duration of symptoms was significantly shorter (Figure 1).

Figure 1. The Effect of EpiCor® on the Number of Days of Sickness Experienced



STUDY OF EPICOR EFFECT ON sIgA

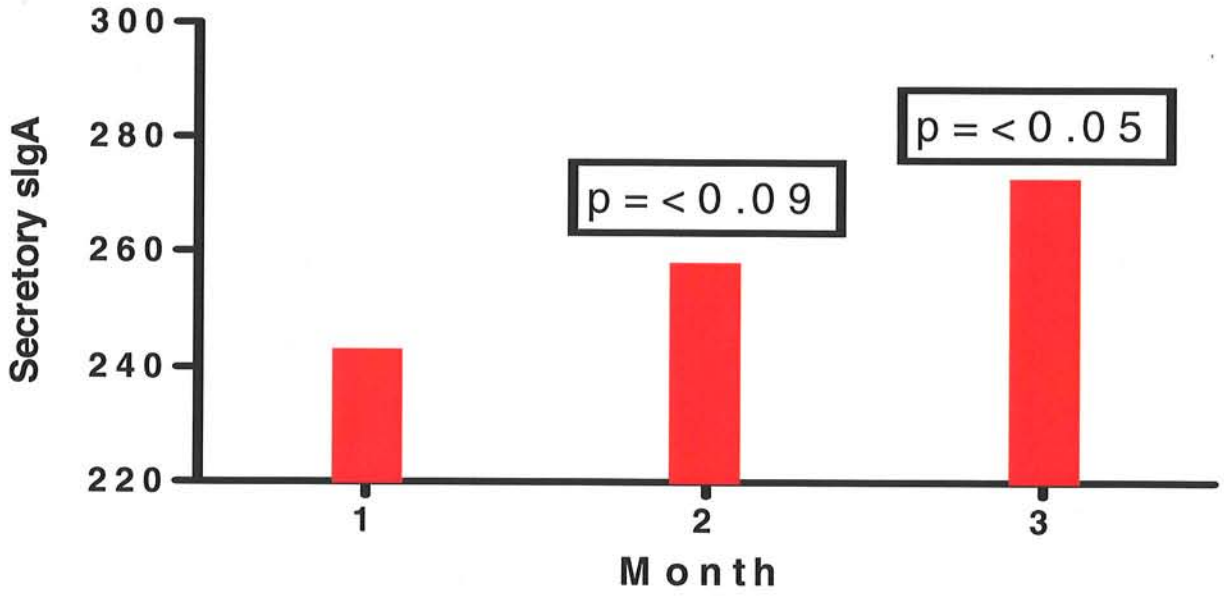
Secretory immunoglobin A (sIgA) is an antibody that is part of the human body's first line of defense and integral to a healthy immune system. This antibody is produced from the gut-associated lymphoid tissue (GALT), which comprises over 70% of the total immune system. As the majority of human infections come via breathing and eating, it is a major part of the body's initial immune defense to adverse conditions. Accordingly, Embria sponsored a human clinical trial

to establish whether EpiCor provides immune support by causing beneficial sIgA levels to increase over a period of weeks.

Twenty-two people were recruited who had never taken EpiCor. Before subjects consumed any EpiCor in this open-label in-house trial, baseline concentrations were established for secretory IgA (sIgA) by measuring saliva samples, which were collected twice a day, three times a week, for one month. The subjects were then given one 500 mg capsule of EpiCor per day for 60 more days while researchers continued monitoring sIgA levels.

After 30 days, results showed a strong trend for increased sIgA over baseline, and after 60 days the average sIgA levels among the subjects were significantly higher than the baseline levels (Figure 2). These results indicate EpiCor increased this important immune defense component in just a matter of a few weeks. It also suggests that it takes time for the body to obtain the full benefits from EpiCor, and that continuous use is needed for the most beneficial effects.

Figure 2. The Effect of EpiCor® on Salivary Secretory IgA



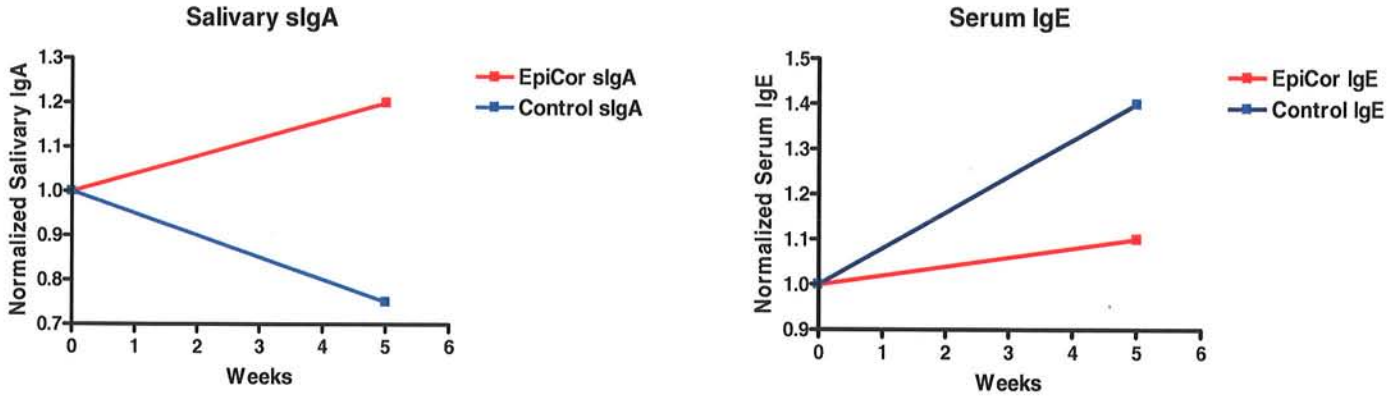
STUDY OF BALANCING EFFECT OF EPICOR ON sIgA AND sIgE

An equally relevant human clinical trial investigated the effects of EpiCor on several known markers of immune function. In this double-blind placebo-controlled trial, subjects were given either EpiCor (500 mg) or placebo for five weeks. At the end of five weeks, the salivary sIgA increased while Serum Immunoglobulin E (sIgE) decreased. Though not reaching full statistical

significance due to both the small number of subjects and the shortness of the trial, this was a strong trend and is hence very encouraging.

These results help confirm the results of other trials demonstrating the efficacy of EpiCor. At the same time, the observation of decreased serum IgE in the EpiCor group suggests the important immune balancing effects of EpiCor. Specifically, since this trial was conducted in the spring when allergies are a problem for many people, it is logical to expect an increase in sIgE because this immune parameter is associated with allergies. In fact, such an increase in sIgE was seen in the results from the subjects receiving the placebo. The EpiCor group, however, had sIgE levels stay nearly at baseline, giving laboratory confirmation of the subjects' reporting fewer allergy problems than usual (Figure 3). Moreover, this is reflected in the standardized questionnaire showing significantly fewer health complaints from the EpiCor group.

Figure 3. The Effect of EpiCor® on Salivary IgA and Serum IgE



It was also observed in this trial that cytokine profiles were shifting in the EpiCor group – from T-helper 1 (Th1) (pro-inflammatory) to T-helper 2 (Th2) (pro-adaptive) and vice versa – again demonstrating the immune balancing properties of EpiCor. This result is consistent with EpiCor research using animal models that also demonstrated the multiple effects of EpiCor and its ability to help balance the immune system and prevent over-reaction in any direction.

SUMMARY OF EPICOR EFFICACY SHOWN IN HUMAN CLINICAL TRIALS

The results from these three clinicals demonstrate the potential for EpiCor to play a beneficial role in helping healthy individuals maintain immune balance. EpiCor has been shown to have a positive effect on key parts of the immune system that perform important functions against challenges. Embria's commitment to science ensures continued responsible research into EpiCor and its benefits.