**Summary of two clinical trials:**


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**Introduction**

These randomized double-blind placebo-controlled human clinical trials examined the effects of EpiCor® postbiotic on the incidence and duration of cold and flu symptoms on non flu-vaccinated and flu-vaccinated subjects.

**Flu-Vaccinated Trial: Key Findings**

- Cold and flu-like symptom clinical occurrences, as recorded by subjects, were significantly lower with EpiCor® postbiotic vs placebo over 12 weeks (1.26 vs 1.42 days; p=0.011).
- Duration of cold and flu-like symptoms were significantly lower by 17% with EpiCor® postbiotic vs placebo (4.16 vs 5.01 days; p=0.028).
- Reduced symptoms of hoarseness, nasal stuffiness, and duration of feelings of weakness with EpiCor® postbiotic vs placebo (p=0.008).

**Non Flu-Vaccinated Trial: Key Findings**

- Cold and flu symptoms clinical occurrences, as recorded by subjects, were significantly lower with EpiCor® postbiotic vs placebo over 12 weeks (1.32 vs 1.5 days; p=0.01).
- There were no significant reductions in duration or severity of symptoms between intervention and placebo.

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**Method**

**Flu-Vaccinated Trial:** This was a 12-week trial conducted during the cold and flu season: December 2006 through March 2007. The subjects were 130 healthy adults, ages 18-76 (mean 44 ± 11), who had been vaccinated against that season's influenza virus. 116 subjects finished the trial with 52 taking 500 mg/day EpiCor® postbiotic and 64 taking placebo.

**Non Flu-Vaccinated Trial:** This was a 12-week randomized, double-blind, placebo-controlled trial conducted during the cold and flu season: January through March. The subjects had not been vaccinated against that season's influenza virus. 116 healthy adult subjects were enrolled in the trial 58 (mean age 37.1) taking 500 mg/day EpiCor® postbiotic and 58 (mean age 39.6) taking placebo. There were two dropouts in the EpiCor® postbiotic group and one dropout in the placebo group due to lack of clinical protocol compliance.
In both trials the recording of common cold or influenza-like symptoms was primarily based on self-report diaries. The following symptoms were self-assessed on a 0-10 point scale for severity (0 = no symptom; 10 = most severe): headache, general aches and pains, fatigue, weakness, nasal stiffness, nasal drainage, sore throat, cough, hoarseness, chest discomfort and chills; any fever, including the temperature, was also recorded. Incidence, duration and severity of these symptoms can be used to clinically define either a common cold or influenza infection (Centers for Disease Control and Prevention. 2007).

Incidence of symptoms was defined as the number of clinical occurrences self-reported during the entire 12-week study period. Duration of symptoms was defined as the number of consecutive illness days.

Results

**Flu-Vaccinated Trial:** The EpiCor® postbiotic group had statistically significantly reduced number of incidences of cold and flu symptoms compared to placebo (p=0.011) (Figure 1). The EpiCor® postbiotic group had 1.26 clinical occurrences (95% confidence interval (CI) 1.18 – 1.33) and placebo had 1.42 (95% CI 1.32 – 1.53).

The average number of days with symptoms was significantly reduced by 17% (p=0.028), an average of 4.16 symptom days (95% CI 3.66 – 4.66) with EpiCor compared to the placebo average of 5.01 symptom days (95% CI 4.40 – 5.62).

**Non Flu-Vaccinated Trial:** The EpiCor® postbiotic group had statistically significantly reduced number of incidences of cold and flu symptoms compared to the placebo (p=0.01) over the course of the study. The EpiCor® postbiotic group had 1.32 clinical occurrences (95% CI 1.25 – 1.39); the placebo group had 1.51 (95% CI 1.37 – 1.65). There were no statistically significant reductions in duration or severity of symptoms between intervention and placebo.

Conclusion

These clinical studies suggest that daily supplementation with 500 mg EpiCor® postbiotic may reduce cold and flu symptom incidence.

Questions? Email EpiCorSales@cargill.com for more information.