Ginseng Extract: Immune System Builder

Walter Alexander

OLD-FX Pharmaceuticals (USA) Inc., based in New York, has launched OLD-FX, a dietary supplement intended to strengthen the immune system. The company is a wholly owned subsidiary of CV Technologies of Edmonton, Canada.

The product’s active ingredient—CVT-E002—is a patented natural extract composed of unique poly-furanosyl-pyranosyl-saccharides that have been isolated from Panax quinquefolius, the North American ginseng root. The product is indicated for healthy adults and children aged 12 years or older.

CV Technologies states that its precise manufacturing processes ensure batch-to-batch measurable chemical and biological consistency. The company’s founder, Chief Executive Officer and Chief Scientific Officer Jacqueline Shan, PhD, noted that in 2001–2002, the company became the first to successfully complete a U.S. Food and Drug Administration (FDA)—regulated phase 2 clinical trial with an herbal product. The company emphasizes that it is committed to a pharmaceutical model with rigorous testing for its development process.

According to company data, CVT-E002 differs substantially from generic ginseng and has beneficial effects on both innate and acquired immune responses. In experimental and in clinical studies, it was able to activate macrophages, releasing interleukins 1 and 6 (IL-1 and IL-6), tumor necrosis factor-alpha, and nitrous oxide. The release of these substances:

- increases antigen-specific, interferon-gamma (IFN-γ)—producing natural killer cells.
- up-regulates antigen-specific T-helper type 1 (Th1) immunity by stimulating lymphocyte production of IL-2 and IFN-γ.
- activates viral antigen–specific CD4+ and CD8+ T cells.

OLD-FX has been evaluated in seven clinical trials that included 679 participants. Two pivotal double-blind, placebo-controlled, randomized trials were conducted in a nursing home for the elderly; another study evaluated healthy adults 18 to 64 years of age. Both trials revealed statistically significant improvements in respiratory health: 89% in the nursing-home trial and 56% in the second trial. The study of healthy adults also noted a decrease in the average number of colds and a reduction in the severity and duration of symptoms.

The nursing-home trial, which was initiated at the onset of the influenza season, included 323 subjects, 18 to 65 years of age, with a history of at least two colds during the previous year. The participants were instructed to take two capsules per day of either CV Technologies’ North American ginseng extract or placebo for four months. The primary endpoint was the number of verified colds. Secondary outcomes included symptom severity on a 4-point scale, the total number of days of symptoms, and the duration of all colds.

Among 279 evaluable subjects, the mean number of colds per person over the four-month period was 0.93 for the placebo group and 0.68 for the group receiving ginseng extract; the result was a significant reduction in the number of colds for ginseng extract ($P = .017$).

Fewer subjects in the ginseng group contracted at least one cold (54.6% vs. 63.8% in the placebo group; $P$ = not significant), and fewer subjects in the ginseng group had recurrent colds (10% vs. 22.8% with placebo; $P = .004$).

The total symptom score for all colds in the study period also favored ginseng extract ($P = .002$), as did the total number of days that symptoms were experienced ($P < .001$). The interventions were generally well tolerated.

The authors concluded that ginseng extract appeared to be an “attractive natural prophylactic treatment” for patients with upper respiratory tract infections. They called for further study in children and immunocompromised populations.

REFERENCES