A Randomized, Placebo-Controlled, Multicenter Study of <i>Ganoderma lucidum</i> (W.Curt.:Fr.) Lloyd (Aphyllophoromycetidae) Polysaccharides (Ganopoly®) in Patients with Advanced Lung Cancer

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ABSTRACT
Preclinical studies have established that the polysaccharide fractions of <i>Ganoderma lucidum</i> (Ling Zhi, reishi mushroom) have potential antitumor activity. Recent clinical studies have demonstrated that <i>G. lucidum</i> polysaccharides enhanced host immune functions (e.g., enhanced natural killer cell activity) in patients with advanced solid tumor, although objective response was not observed. A randomized double-blind, placebo-controlled, multicenter clinical trial was conducted to evaluate the efficacy and safety of the <i>G. lucidum</i> polysaccharides, Ganopoly®, in patients with advanced lung cancer. Sixty-eight patients with histologically confirmed advanced lung cancer were enrolled. Eligibility criteria included con. mation of diagnosis, objective measurable disease, a Karnofsky performance score $\geq 60$, life expectancy of 12 weeks or greater, no recent or concomitant anticancer therapy, and informed consent. Patients were evaluated with respect to their extent of disease and quality of life (Karnofsky score), and hematologic and immunological changes. A statistically significant increase in lymphocyte mitogenic reactivity to CD14 (21.9%) patients receiving Ganopoly had unchanged and reduced KPS scores, respectively. Values were 13 (46.4%) and 11 (39.3%) in the control group.

Insomnia: 1) were recorded in patients receiving Ganopoly, and one episode of toxicity (vomiting) was recorded in the control group. The results indicate that Ganopoly may have an adjunct role in the treatment of patients with advanced lung cancer. Further studies are needed to explore the optimum dosing, efficacy, and safety of Ganopoly when used alone or in combination with chemotherapy/radiotherapy.