

HerbalScience Releases Results of Pilot Clinical Study on Efficacy of Its Proprietary Elderberry Extract in Addressing Flu-Like Symptoms

--Article in Online Journal of Pharmacology and Pharmacokinetics Details Placebo-Controlled, Double-Blind Trial Showing Clear Reduction of Symptoms with Elderberry Extract --

NAPLES, Fla., Oct. 6 /PRNewswire/ -- The ability of a proprietary elderberry extract to significantly reduce flu-like symptoms was demonstrated in a double-blind, placebo-controlled study, undertaken on behalf of HerbalScience Group LLC. The pilot, randomized clinical trial was conducted by Dr. Fan-kun Kong, assisted by medical personnel at Shanghai Construction Technical College, China. The study took place during the spring 2009 flu season and involved 64 patients ranging in age from 16 to 60 years.

At the time of enrollment in the study, each of the 64 patients had had three or more flu-like symptoms (fever, headache, muscle aches, coughing, nasal mucus discharge, and nasal congestion) for less than 24 hours. Patients were randomized into two groups and for two days were given four doses daily of the proprietary elderberry extract developed by HerbalScience or a placebo. Patients were asked to self-assess their symptoms at specific intervals over the two days, scoring the severity of symptoms on a Visual Analogue Scale (VAS), with "0" equal to no problem and "10" equal to a pronounced problem.

"By 48 hours, nine patients (28%) in the group receiving the elderberry extract were symptom-free, 19 patients (60%) showed relief from some symptoms and had only one or two mild symptoms (VAS=1), while the remaining four showed symptom improvement but to a lesser degree," said Dr. Kong. "By contrast, complete recovery was not achieved by a single patient in the placebo group, and only 16% showed improvement in one or two symptoms. For most in the placebo group, symptoms remained the same or even worsened over the 48-hour period."

An article by Dr. Kong detailing the clinical study has been published in the peer-reviewed scientific journal *Online Journal of Pharmacology and Pharmacokinetics*. Dr. Kong holds a Ph.D. in Immunology from the University of Alabama at Birmingham and an M.D. from Hunan Medical University, People's Republic of China. He conducted the study on behalf of HerbalScience Group, a Naples, Florida, and Singapore-based company dedicated to applying advanced science and technology to the production of botanical drugs and nutraceuticals.

The elderberry extract used in the clinical trial was created by HerbalScience using a proprietary extraction technology that enables the company to standardize the chemical profile of any selected botanical in order to deliver a compositionally and functionally consistent product batch to batch and dose to dose. The patented technology was developed for the company by top researchers in the areas of botanical and natural products chemistry and plant biology, as well as leading experts in supercritical CO₂ and affinity absorbent extraction technologies, methods used for extracting plant chemicals.

In addition, the use of an advanced DART (Direct Analysis in Real Time) Time-of-Flight mass spectrometer enabled HerbalScience to detect, identify with high accuracy, and quantify the hundreds of individual chemicals present in the

extract, including identification of the key bioactive compounds. Laboratory studies conducted prior to the pilot clinical trial had previously demonstrated *in vitro* antiviral activity of the proprietary elderberry extract.

For the clinical trial, HerbalScience formulated its elderberry extract as a slow-dissolve lozenge containing 175 mg of the extract plus non-active ingredients. The placebo lozenges used were identical in appearance, taste, and composition except that there was no elderberry extract included. The packages for both the elderberry extract lozenges and placebo lozenges were labeled only with numbers and the contents blinded to the investigator, doctor, and patients.

Following the first 24 hours of treatment, the proprietary elderberry extract group showed a statistically significant reduction in fever, headache, muscle aches, and nasal congestion, and some improvement in nasal mucus discharge. Within 48 hours, all patients in the elderberry group had returned to normal temperature, and 78% were headache-free, with 22% reporting only mild headaches. Additionally at 48 hours, 87% had recovered from muscle aches; 50% were free of nasal congestion; and 50% reported no nasal mucus discharge, with the other 50% reporting only mild symptoms. Coughing was the only symptom that showed no significant improvement in 24 hours, but in 48 hours, 31% of patients in the elderberry group were relieved from coughing and 37% showed symptom improvement.

By contrast, in the placebo group, the majority of patients failed to show any improvement in fever within the 48-hour treatment period and headaches became more severe for most patients. The placebo group also reported a worsening of muscle aches at 48 hours, and nasal congestion also worsened in 93% of this group. Only one out of 16 (6%) of the placebo group reported improvement in nasal mucus discharge at 48 hours; and two patients (13%) showed slight symptom improvement in coughing, while the remainder worsened.

"Elderberry, as a folk medicine, has a long history of being used to treat colds and flu, and in this clinical study, the proprietary elderberry extract was shown to be both safe and effective in controlling flu-like symptoms," said Dr. Kong. "The safety and ease of administration clearly warrant further investigation of its clinical efficacy in children, the elderly, and other high-risk patients, as well as additional studies involving a larger patient population."

The article detailing the clinical trial, authored by Dr. Kong and titled "Pilot Clinical Study on a Proprietary Elderberry Extract: Efficacy in Addressing Influenza Symptoms," was published in *Online Journal of Pharmacology and Pharmacokinetics*, Volume 5: 32-43, 2009.

HerbalScience Group LLC is a privately-held life sciences company headquartered in Naples, Florida, with facilities in Singapore. HerbalScience is engaged in the discovery, development, manufacture, and marketing of proprietary botanical compounds for human health in the U.S. and international markets. The company has prominent alliances with prestigious university laboratories and prominent researchers in the U.S., as well as research institutions in China.

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