

## For Immediate Release

### First Ever Homeopathic Study Based on Modern Scientific Methodology Published in AMA Journal

— VERTIGOHEEL® Shown to be Safe and Effective in the Treatment of Vertigo —

ALBUQUERQUE, N.M., August 13, 1998 - A study published in the August issue of the American Medical Association journal *Archives of Otolaryngology - Head and Neck Surgery* shows that VERTIGOHEEL®, a prescription homeopathic medication, is as effective and safe as betahistine, a histamine analogue considered standard therapy in Europe for the management of vertigo symptoms. The publication of this study in an AMA journal reflects the growing interest in homeopathic medicine. In fact, in the July 15, 1998 issue of the *Journal of the American Medical Association (JAMA)*, a survey of readers identified "alternative medicine" such as homeopathy, as one of the top ten topics of which more information should be published.

Vestibular or balance disorders such as vertigo, dizziness, and motion sickness affect approximately two million people in the U.S. Despite the severity of vertigo, American physicians lack a conventional medication proven to be an effective treatment for the disease. This study represents the first equivalence trial comparing a homeopathic treatment for vertigo to standard drug therapy.

"This is the first time that the AMA has published a study of a homeopathic drug - a study that was designed according to modern scientific methodology," said Dana Ullman, MPH, president of the Foundation for Homeopathic Education and Research and author of numerous books on homeopathy. "Other respected, peer-reviewed medical publications such as *The Lancet*, *Pediatrics*, and *British Medical Journal* are now joined by the AMA's *Archives of Otolaryngology* in their scientific review of homeopathic studies."

The year-long, double-blind, randomized, controlled clinical trial compared the efficacy and safety of VERTIGOHEEL® with betahistine. The study included 119 male and female patients with acute or chronic vertigo symptoms of various origins. The clinical trial was conducted from 1995 to 1996 at 15 medical clinics throughout Germany. In accordance with good clinical practices, patients were assigned to one of two treatment groups: the VERTIGOHEEL® group or the betahistine group. Patients in both groups were given 15 drops three times per day of the active drug (VERTIGOHEEL® or betahistine) for 42 consecutive days.

#### Study Results

The primary efficacy variables for the study were the frequency, duration, and intensity of vertigo attacks. After six weeks, vertigo-specific complaints were significantly reduced in both treatment groups. VERTIGOHEEL® and betahistine were therapeutically equivalent in reducing the duration and intensity of vertigo attacks. Although not clinically significant, VERTIGOHEEL® was marginally superior to betahistine in reducing the frequency of vertigo attacks.

The study's secondary efficacy variables involved quality of life measurements, including physical health and mental activity, from the patients' point of view. These were assessed using the standardized MOS-SF36 validated quality of life questionnaire as well as a four-part vertigo-specific questionnaire. The patients' and investigators' global assessment of efficacy also comprised the study's secondary efficacy variables. There was an increase in the patients'

quality of life and a significant decrease in vertigo-specific symptoms in both treatment groups. According to investigators, more than 70 percent of patients in both of the VERTIGOHEEL® and betahistine groups reported a significant improvement in quality of life. In addition, for more than 90 percent of study patients in both treatment groups, the tolerability of both drugs was rated as "good" or "excellent."

Clinical laboratory data and vital signs for each patient remained essentially unchanged throughout the course of the study, indicating a favorable safety profile for both VERTIGOHEEL® and betahistine.

"These results establish VERTIGOHEEL® as a safe and effective treatment for vertigo," said study investigator Michael Weiser, PhD, Director of Clinical Research, Heel, GmbH. "VERTIGOHEEL® was shown to be as effective as betahistine, a standard anti-vertigo drug, in significantly reducing the frequency and severity of vertigo attacks and was also very well-tolerated. Because of the lack of effective conventional treatments, VERTIGOHEEL® fills a serious void for treating millions of Americans suffering from vertigo and other types of dizziness."

"We are excited about the publication of this head-to-head clinical comparison in an American Medical Association (AMA) journal," said Perry Pedersen, Vice President, General Manager, Heel Inc., the U.S. manufacturer and exclusive distributor of VERTIGOHEEL®. "Not only does it prove that VERTIGOHEEL® is an effective and safe drug for treating vertigo, but it also demonstrates why homeopathic drugs are gaining acceptance among patients

and medical practitioners throughout the world. The fact that such a study has been published in an AMA journal is a landmark in itself. The clinical utility of homeopathic drugs like VERTIGOHEEL® is now being objectively assessed by our most respected medical institutions."

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#### About Vertigo

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Vertigo is a condition where sufferers experience a false sensation of motion - either horizontally or vertically. It is a disorder of the body's vestibular system, which is located in the inner ear and responsible for maintaining equilibrium. Although many of the causes of vertigo are unknown, the most common causes include head trauma or whiplash, migraine, advanced age, ear infections, viruses, high doses or long-term use of certain antibiotics, stress and fatigue, and stroke or conditions resulting in

reduced blood flow to the inner ear or brain. Vestibular disorders, which also include motion sicknesses (e.g., car sickness and sea sickness), are among the most common reasons for doctor visits, with U.S. physicians reporting more than five million related visits per year.

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#### About Heel Inc.

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VERTIGOHEEL® is manufactured and distributed in the U.S. by Heel Inc., a marketer and manufacturer of combination homeopathic remedies based in Albuquerque, NM. Heel Inc. is also the U.S. distributor for its parent company, Heel GmbH in Baden-Baden, Germany, the world's largest manufacturer and marketer of combination homeopathic pharmaceuticals, distributing products in over 55 countries. Heel Inc. manufactures and markets over-the-counter (OTC) and prescription pharmaceuticals (including

injectables) according to the regulatory requirements for homeopathic drugs as defined in the 1938 Food, Drug and Cosmetic Act, the FDA's 1988 *Compliance Policy Guides - Conditions Under Which Homeopathic Drugs May be Marketed*, the Homeopathic Pharmacopoeia Convention of United States (HPCUS), and local health agencies (e.g., the New Mexico State Board of Pharmacy). Unlike classical homeopathic drugs, the active ingredients in products such as VERTIGOHEEL® are not ultra-highly diluted and the pharmacological and clinical profiles can be defined within the conventional medical paradigm. The products of Heel Inc. represent a bridge between classical homeopathy and conventional pharmacology.

For full prescribing information about VERTIGOHEEL®, please see page 1187 of the 1998 *Physicians' Desk Reference*.