BeneChill, Inc. Announces Positive Results from COOLHEAD Clinical Study

Intranasal Evaporative Cooling Benefits Migraine Patients

San Diego, CA - February 4, 2015 - BeneChill, Inc. (“BeneChill”, the “Company”) announced positive results from the COOLHEAD Clinical Study. The purpose of the study was to determine the effectiveness of intranasal evaporative cooling for the treatment of acute migraine headaches.

The open-label, observational study consisted of 15 adult patients (M=3, F=12) with an average age of 43 years. All patients satisfied the International Classification of Headache Disorders (ICHD 2) criteria for either episodic (with or without aura), or chronic migraine. Patients in this trial were categorized as having severe migraine with 93% recording a normal historical duration of pain and symptoms of more than 24 hours, when using standard treatments, while 46% of the patients had typical migraines lasting up to 72 hours. The historical baseline of migraine Pain Severity (VAS 0-10 with 0 = no pain/discomfort and 10 = severe pain/discomfort) for this patient group averaged a score of 8, with modes of 9 and 10. All patients stated that they had multiple migraine attacks per month.

The study protocol was designed for patients to receive 1 treatment per migraine incident. Patients could be treated for multiple migraines throughout the study’s duration. A total of 20 treatments were provided (12 patients received 1 treatment, 3 patients received 2 treatments, and 1 patient received 3 treatments).

BeneChill’s products consist of a portable control unit, a nasal catheter and a bottle of cooling fluid. A maximum intranasal cooling period of 20 minutes was allowed per treatment; however, the average treatment time delivered was 15 minutes of cooling.
The study was investigator initiated and led by consultant neurologist, Dr. Jitka Vanderpol. The site was the Penrith Community Hospital, part of the Cumbria Partnership NHS Foundation Trust, located in the North West of the United Kingdom.

Primary endpoints for the COOLHEAD Clinical Study were the reduction in pain and in associated symptoms. Results were positive for both. Complete or partial pain relief was reported in 13 of the patients (87%). Treatments offered the patients either complete relief (40%) or partial relief (50%) from pain and associated symptoms after a mean treatment duration of 15 minutes. Furthermore, 90% of all patients experienced either full or partial relief at 2 hours post treatment. Eighty-seven percent (87%) experienced sustained relief 24 hours post treatment.

Additionally, BeneChill’s migraine therapy reported no major adverse side effects. In comparison to current relief therapies (including triptan drugs, cool packs, and other prescription analgesics), 60% of patients reported that BeneChill’s intranasal cooling offered better results. Twenty-six percent (26%) stated that intranasal cooling was as good as their current medication, but with less side effects. The patients who preferred intranasal cooling therapy cited that their preference was based on intranasal cooling providing significantly faster relief from pain and symptoms than their existing medication and/or remedies. The patients who usually take triptan medications also noted that they did not suffer from any of the debilitating side effects that they encounter after taking their normal rescue medication, which "knocks me out".

“The COOLHEAD Study's findings are very promising. Our initial experience has demonstrated that intranasal cooling is safe, effective, quick and well tolerated. While intranasal cooling is a novel approach, it has been shown to offer faster relief for those suffering from severe, recurrent, and long-lasting migraines. Furthermore, the intranasal cooling therapy has additional benefits in that it is comfortable for the patient and is not associated with numerous negative side
effects experienced with use of abortive triptan drugs. A larger, multi-site clinical trial will be planned to provide further evidence of the benefits from this application,” stated Fred Colen, Chief Executive Officer of BeneChill.

The full COOLHEAD Clinical Study can be found in the Journal of Headache and Pain or by clicking here.

About BeneChill, Inc.

BeneChill, Inc. is a medical device company established in 2003 to develop, manufacture, and sell novel rapid cooling products to improve clinical outcomes. BeneChill’s lead product, the RhinoChill® IntraNasal Cooling System (also referred to as the RhinoChill® System, “RhinoChill®”, or the “System”), is designed to deliver targeted, effective and therapeutically beneficial cooling to the nasal cavity and the brain (and to the body via the cooled brain, if so desired). BeneChill’s technology is intended to protect the brain through reduction of brain oxygen demand, reduction of brain swelling, and minimizing the impact of hypoxic brain injury significantly earlier and in a more effective manner compared to current methods. Utilizing a lightweight, portable system design and unique intra-nasal, catheter-based delivery of a quickly evaporating coolant, BeneChill enables a range of medical professionals including first responders, emergency room personnel, and surgeons a unique opportunity to start protecting the brain. BeneChill’s treatment can be used during Cardiac Arrest, potentially during Traumatic Brain Injury and may be applicable for other surgical procedures. BeneChill’s cooling technology, however, is not only designed for brain protection applications for unconscious or sedated patients, it is also suitable for applications on conscious patients where a local, short duration cooling of the nasal cavity is of therapeutic benefit, such as for the treatment of acute migraine. BeneChill is headquartered in San Diego, CA with European locations near Zürich, Switzerland and Düsseldorf, Germany. BeneChill products, while CE marked in Europe for cooling applications are not FDA approved and not available in the US. For further information please visit www.benechill.com.

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BeneChill, Inc. Contact:

Fred Colen, Chief Executive Officer  
(858) 695-8118  
fcolen@benechill.com  
or  
Investor Relations Contact:  
Jennifer K. Zimmons, Ph.D., Investor Relations  
(917) 214-3514  
jen@benechill.com  
www.benechill.com

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