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MedInvent announces first outcomes data for the NasoNeb® Nasal Nebulizer

April 15, 2013. Orlando, FL: The first outcomes trial[2] of the NasoNeb® Nasal Nebulizer was presented at the Combined Otolaryngology Society Meeting 2013 in Orlando, FL.

This 40 patient, parallel, randomized, double-blind, placebo-controlled, pilot study included 20 patients in the placebo arm and 20 patients in the treatment arm. The study participants in the placebo arm were given 2.5 ml of 0.9% saline delivered via the NasoNeb Nasal Nebulizer. The study participants in the treatment arm were given 2.5 ml (0.25mg) of Budesonide in the form of Pulmicort respules delivered via the NasoNeb Nasal Nebulizer. Each arm was treated twice a day for 26 days. All study subjects had perennial allergic rhinitis.

Objective and subjective measures including nasal peak inspiratory flow (NPIF) and nasal symptoms (graded on a 0-3 scale) were recorded by the subjects twice daily. Rhinoconjunctivitis quality of life (QOL) as well as nasal volume, measured by acoustic rhinometry, was obtained at baseline, after 2 weeks, and at the end of treatment. NasoNeb demonstrated improvements in objective and subjective outcome measures from baseline to endpoint in the treatment arm and when compared to the placebo arm.

The treatment arm demonstrated a statistically significant increase ($p<0.005$) from baseline to endpoint in nasal peak inspiratory flow (NPIF). NPIF measured between the treatment and placebo arms had a p-value = 0.099, just missing statistical significance. This is likely due to the low number of patients in the pilot study and the authors suggest that the placebo used (0.9% saline) has been shown to have a clinical effect of its own. The authors concluded that the patients demonstrated clinically-significant improvements.

“Clinical evidence continues to build for the NasoNeb Nasal Nebulizer. Coupled with peer-reviewed, published, as well as previously presented deposition data on the NasoNeb Nasal Nebulizer[1, 3], this outcomes data strengthens the role of NasoNeb-delivered topical therapies for rhinologic conditions. NasoNeb clearly stands out as the only device on the market with positive clinical data” commented William Flickinger, CEO, MedInvent, LLC.

The study was supported by a grant from MedInvent, LLC. The abstract is available on-line at http://www.cosm.md/abstract/2013program.pdf.

The NasoNeb Nasal Nebulizer is available by prescription through The NasoNeb Pharmacy Network℠, a network of compounding pharmacies across the US.

For more information, please visit the MedInvent, LLC website at www.nasoneb.com.

Referenced Studies

1. Yuri M. Gelfand, MD; Samer Fakhri, MD; Amber Luong, MD, PhD; Seth J. Isaacs, MD & Martin J. Citardi, MD: “A Comparative Study of the Distribution of Normal Saline Delivered by Large Particle Nebulizer vs. Large Volume/Low Pressure Squeeze Bottle” 56th Annual Meeting of the American Rhinologic Society, September 25, 2010, page 38

2. Kristal Brown MD, James Lane BSc, Marianella Paz Silva, MD, Marcy DeTineo BSN, Robert M. Naclerio MD, and Fuad M. Baroody, MD: “Effects of Intranasal Budesonide Delivered by Nasal Nebulizer on Symptoms and Objective Measures of Nasal Congestion in Perennial Allergic Rhinitis” COSM 2013 Program, p 22

3. Manes RP, Tong L, Batra PS.: “Prospective evaluation of aerosol delivery by a powered nasal nebulizer in the cadaver model” Int Forum Allergy Rhinol, 2011; 1:366–371

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About MedInvent, LLC

MedInvent, LLC is a privately-held limited liability corporation established in 2008 with operations in White Bear Lake, MN. MedInvent manufactures and markets the NasoNeb Nasal Nebulizer for the topical delivery of medication to the nasal and paranasal sinus cavities. The NasoNeb Nasal Nebulizer is indicated for topical drug delivery to the nasal cavity for drugs formulated for inhalation.

Contact William Flickinger at 651-236-8545 for more information or visit website at www.nasoneb.com

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