First Patient Enrolled in Phase III Studies Using OptiNose's Novel Breath Powered™ Device to Deliver Fluticasone Intranasally for Treatment of Nasal Polyps

Comprehensive clinical program is designed to support registration of OPN-375 (Fluticasone delivered with OptiNose's Novel Breath Powered™ intranasal delivery device) in the United States and build on company's mission to transform the static nasal drug delivery market

YARDLEY, Pa.—October 31, 2013—OptiNose Inc. announced today enrollment of the first patient into the NAVIGATE trials, two large phase III clinical trials of fluticasone delivered using OptiNose's novel Breath Powered™ intranasal delivery system (OPN-375) for the treatment of nasal polyps. Building on the promising results of an earlier phase II study, which found a high degree of efficacy and even some polyp elimination[1], NAVIGATE I & II are controlled trials designed to more definitively evaluate the efficacy and safety of three doses of fluticasone (100, 200, and 400 µg twice a day) delivered in a new way with the innovative OptiNose technology to treat patients with nasal polyps.

To view the multimedia content, please click: http://www.multivu.com/players/English/57713-optinose-innovative-breath-powered-nasal-delivery-technology-delivers-drugs-to-treat-variety-of-medical-conditions.

Nasal polyps are growths on the lining of the nasal cavity and/or sinuses which may cause nasal obstruction, reduced sense of smell, pain, headache, snoring, difficulty breathing and a variety of other symptoms which can negatively affect quality of life. These symptoms last for months or many years, and despite currently available medical treatments, patients with nasal polyps often require surgery. Even after treatment, including surgery, nasal polyps often return and require ongoing treatment or repeated surgery. Fluticasone is a topical corticosteroid that will prevent and decrease the inflammation associated with this disease when properly delivered to the affected areas.

"Existing methods for treating nasal polyps are limited, and there is a need for improved and alternative options," stated Donald Leopold, M.D., Professor, University of Vermont College of Medicine, and lead principal investigator for one of the two identically designed studies. "The nasal cavity is complex, making it hard to deliver drugs to the right place. OptiNose's Breath Powered delivery system represents an innovative way to deliver fluticasone to hard-to-reach areas to treat nasal polyps."

NAVIGATE I & II are randomized, double-blind, placebo-controlled, multicenter, international studies designed to assess the efficacy and safety of OPN-375 (at doses of 100, 200, and 400 µg twice a day) in patients with bilateral nasal polyposis for 16 weeks, followed by an 8-week open-label extension phase to assess safety.

Two co-primary endpoints will be assessed in the studies: reduction of patient-rated nasal congestion/obstruction symptoms and reduction in total polyp grade, or size, as measured by physicians who examine the polyps through nasal endoscopes. Each study will enroll approximately 320 patients.

“OptiNose has now successfully moved two product candidates – sumatriptan for acute migraine and fluticasone for nasal polyps – into late stage clinical development, demonstrating our expertise in both liquid and powder nasal delivery, and our commitment to developing improved alternatives to existing nasal sprays, tablets and injections,” said Peter Miller, Chief Executive Officer of OptiNose. “We are conducting a comprehensive clinical program in order to generate data needed to bring this new fluticasone-containing product to market, including multiple trials which together are set to enroll over 1,500 patients.”

Additional Studies Underway
To further examine the overall safety profile and support a future launch of this new product, the development program also includes two additional phase III clinical studies that are already underway. Each study is an open-label, multicenter study evaluating the safety and tolerability of a 400 µg dose of OPN-375 given twice daily for treatment of patients with chronic sinusitis, with or without nasal polyps. One study will evaluate approximately 700 patients for three months, and the other will evaluate approximately 200 patients for 12 months.

Safety will be assessed throughout each of these studies by measures such as monitoring adverse events, performing nasal and ocular examinations, measuring vital signs (e.g., blood pressure, pulse), and through collection of information on the use of other medications (e.g., “rescue medication”). OptiNose is planning to have results from all the studies in this research program by late 2014 or early 2015.

About Nasal Polyps
The prevalence of nasal polyps among the general population ranges from one percent to four percent, with approximately 200,000 new symptomatic cases of nasal polyps reported every year in the United States.[2,3] The incidence of nasal polyps increases from the age of 30 and the disorder is more common among men than women.[3]

About OptiNose Breath Powered™ Delivery Technology
OptiNose’s Breath Powered delivery technology is unique in that it uses the natural function of a user’s breath to propel medications beyond the nasal valve into the deep, targeted areas of the nasal cavity more effectively, efficiently and consistently than current treatments. A user exhales into the device, automatically closing the soft palate and sealing off the nasal cavity completely. The exhaled breath carries medication from the device into one side of the nose through a sealing nosepiece. Narrow nasal passages are gently expanded and medication is transported well beyond the nasal valve to targeted sites. After delivering medication to the targeted sites, air painlessly flows around to the opposite side of the nasal cavity and exits through the other side of the nose rather than into the throat or lungs.

About OptiNose
OptiNose is a drug delivery company developing a breakthrough Breath Powered nasal technology set to transform the static nasal drug delivery market. OptiNose devices are designed to reliably deliver nasal medication to target regions of the nasal cavity, including the sinus and olfactory regions, while preventing lung deposition. The simple devices are intended to unlock the potential for significant new treatment benefits, including better local activity of medications like fluticasone.

OptiNose has created single and multi-use nasal devices for delivering both powder and liquid formulations. The patent-protected technology has been successfully tested in a number of clinical trials evaluating the advantages of the technology compared to traditional nasal sprays. OptiNose is actively developing internal products using the new technology, which is also available to license for delivery of proprietary medicines. In July 2013, OptiNose entered into an exclusive North American license agreement with Avanir Pharmaceuticals, Inc. for the further development and

commercialization of OptiNose's novel Breath Powered intranasal delivery system containing low-dose sumatriptan powder to treat acute migraine.

Investors in OptiNose include Avista Capital Partners in New York, WFD Ventures LLC located in New York and Entrepreneurs Fund LP based in Jersey, Channel Islands. For more information please visit www.optinose.com.

References

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3. Larsen K, and Tos M. The estimated incidence of symptomatic nasal polyps. Acta Otolaryngol 122:179–182, 2002.

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