

## **OptiNose Announces Positive Results of Phase III Trial for OPN-375**

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*OPN-375, in Development for Chronic Rhinosinusitis with and without Nasal Polyps, Demonstrated Statistically Significant Benefits in Patients with Nasal Polyps*

**YARDLEY, PA, June 24, 2015**— OptiNose today announced positive results from its first phase III controlled clinical trial, NAVIGATE II, evaluating the safety and efficacy of OPN-375, an investigational treatment for nasal polyps, a type of Chronic Nasal Inflammatory Disease (CNID), and the associated chronic symptoms. OPN-375 demonstrated statistically significant effects on both co-primary endpoints: reduction of patient-rated nasal congestion/obstruction symptoms ( $P<0.001$ ) and endoscopically measured reduction in total polyp grade ( $P<0.001$ ). Statistically significant benefits were also observed on a wide range of secondary endpoints. The incidence of adverse events with OPN-375 was consistent with the favorable results observed in previous trials.

NAVIGATE II is a randomized, double-blind, placebo-controlled trial that enrolled 323 patients with nasal polyps from 5 countries, including the United States. The study was 24 weeks in duration, with subjects receiving placebo-controlled double-blind therapy for the first 16 weeks followed by treatment with OPN-375 for an additional eight weeks. In addition to the co-primary endpoints, the study also demonstrated statistically significant improvement in the other core symptoms of the disease (nasal drainage, pain and pressure, and loss of sense of smell), and in other common and burdensome symptoms, with the use of OPN-375.

"These are exciting results," said Donald Leopold, M.D., Professor, University of Vermont College of Medicine, Past President of the American Rhinologic Society, and an investigator in the study. "These data suggest that it could make a big difference for patients when we use this new technology to deliver medication to the right areas in the nasal cavity. We are seeing a significant level of relief for patients with chronic symptoms like congestion, many of whom had already tried regular nasal sprays, and in some instances we even saw elimination of polyps."

"If a new treatment can significantly reduce the size of – and in some cases eliminate – nasal polyps, while alleviating chronic inflammation and the core symptoms of chronic nasal inflammatory diseases such as nasal congestion, nasal drip, sinus pain & pressure and loss of smell/taste, it is a significant development in the field," added James Palmer, M.D., Professor and Director of the Division of Rhinology at the University of Pennsylvania in Philadelphia and current Secretary of the American Rhinologic Society, as well as a principal investigator in OPN-FLU-3204, another study in the clinical development program for OPN-375. "I see a huge number of patients who get poor symptom relief using the medications available for long-term treatment today, like ordinary steroid nasal sprays. A new medication that provides significant relief to that patient population would be a great new tool for doctors and patients."

"Chronic nasal inflammatory diseases are an extremely common, if underappreciated, problem and there is surprisingly little late-phase research to develop new treatments. Too many patients with these chronic diseases still have symptoms, despite the availability of current medications. We believe today's results – if confirmed – could be an important step forward in meeting the needs of those patients who are suffering day in and day out with fairly severe symptoms," said Ramy Mahmoud, M.D., MPH, President of OptiNose. "Our team has worked hard to develop OPN-375, and we are excited at the prospect of providing doctors with a potentially important new treatment option for these patients."

### **Background Information**

#### **About OptiNose Technology: Bi-Directional™ Breath Powered™ Drug Delivery Systems**

OptiNose's patented technology for closed-palate Bi-Directional Breath Powered drug delivery systems is unique in that its exhalation devices use the natural functions of a patient's breath to help effectively and efficiently deliver medications beyond the nasal valve into deep, targeted areas of the nasal cavity. A user exhales into the device, naturally closing the soft palate and sealing off the nasal cavity from the throat. The exhaled breath carries medication from the device into one

side of the nose through a specially shaped sealing nosepiece, balancing the pressure on the soft palate. 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 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 OPN-375**

OPN-375 is a unique drug-device combination product that uses OptiNose's patented technology to deliver a highly effective and well-understood topical steroid medication (fluticasone) into the nasal cavity in a deeply distributed manner. Available data, including two published Phase II trials, suggest that OPN-375 has the potential to be a transformational breakthrough in the treatment of serious chronic nasal inflammatory diseases like chronic rhinosinusitis with nasal polyps. A global late-phase clinical program to investigate the use of OPN-375 to treat chronic rhinosinusitis with or without nasal polyps, comparable in scale to that required for a new molecular entity and enrolling over 1,500 patients, is underway. OptiNose is also working to ensure that other critical enablers of future OPN-375 product success, including a launch-ready supply chain and other appropriate pre-commercial efforts, are in place to bring the product to market immediately following regulatory review.

### **About the NAVIGATE I & II Trials**

Two global placebo-controlled studies, NAVIGATE I and II, are being conducted to assess the safety and efficacy of OPN-375 in patients with bilateral nasal polyposis. The trials began enrolling patients in October 2013, and results from both studies are anticipated in 2015.

These two randomized, double-blind, parallel-group, multicenter studies are designed to assess the efficacy and safety of three different doses of OPN-375. Approximately 320 patients have been enrolled in each trial. After 16-weeks of double-blind treatment, there is an 8-week open-label extension to allow additional safety and efficacy assessment. Patients in these trials receive 100, 200 or 400 µg doses of OPN-375 twice daily or placebo. The results from NAVIGATE I are expected later in 2015.

### **About OptiNose**

OptiNose is a Specialty Biopharmaceutical Company developing a promising pipeline of late stage new products. The Company's patented closed-palate Bi-Directional™ Breath Powered™ drug delivery systems enable differentiated treatments using exhaler devices that deposit drugs high and deep in the nose. OptiNose successfully out-licensed a first product at the end of phase 3 (AVP-825 for Migraine, licensed to Avanir in North America, since purchased by Otsuka Pharmaceutical Co., Ltd.), and has reported clinical success with other products, including OPN-375, a treatment in development for Chronic Nasal Inflammatory Diseases (CNID). OPN-375 has potential to create a new standard of care for the treatment of serious CNID, such as Chronic Rhinosinusitis. Other OptiNose pipeline products also target large markets with significant unmet need, including nose-to-brain applications of the technology such as OPN-300 for Autism. OptiNose has corporate offices in the US, Norway and the UK. For more information, please visit [www.optinose.com](http://www.optinose.com).

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.

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