OptiNose Announces Positive Results of Second Phase III Pivotal Trial for OPN-375

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OptiNose Plans to Submit NDA

YARDLEY, PA, September 24, 2015— OptiNose today announced positive results from a second phase III pivotal trial, NAVIGATE I. This follows and helps both to confirm and support the positive results from a first pivotal trial, NAVIGATE II, that were announced in June. The NAVIGATE trials are double-blind, placebo-controlled studies evaluating the safety and efficacy of OPN-375, an investigational treatment for nasal polyposis, a type of Chronic Nasal Inflammatory Disease (CNID), and the associated symptoms of the disease. Key findings from NAVIGATE I include:

- Patients treated with OPN-375 experienced statistically significant benefits on both co-primary endpoints: reduction of patient-rated nasal congestion/obstruction symptoms ($P<0.01$) and endoscopically measured reduction in total polyp grade ($P<0.01$).
- 93% of patients entering the trial had previously used conventional nasal steroids, with 49% of trial participants having used them during the month prior to entry. In this trial, a Patient Global Impression of Change was measured, and 66% of patients receiving OPN-375 reported being "much" or "very much" improved after 16 weeks of treatment. Additionally, >70% of patients were found to have a 1 point or greater improvement in polyp grade, with some (up to 29% of the group using the highest dose tested) found to have complete elimination of polyps in at least one nostril (polyp grade 0) after 6 months.
- Statistically significant benefits were also observed on a range of secondary endpoints, including a designated key secondary measure, the 22-item Sinonasal Outcomes Test. The Sinonasal Outcomes Test showed statistically significant benefit both overall and on subscales such as sleep function and rhinological symptoms.
- The incidence of adverse events with OPN-375 was generally consistent with previous trials, with epistaxis and nasal mucosal disorder being the most frequently reported.
- Overall, the results are consistent with those of the other pivotal trial, NAVIGATE II.

"We believe these results provide validation of the promise of OPN-375 in treating nasal polyps and its potential to be an important new tool in the treatment arsenal for this condition. The positive results further strengthen the growing body of evidence from our ongoing clinical development program for OPN-375 as a potential treatment for chronic rhinosinusitis with or without nasal polyps," said Peter Miller, Chief Executive Officer of OptiNose. "Based on a large population survey, an estimated 28 million adults in the U.S., or approximately one in eight people, suffer from severe chronic nasal inflammatory diseases. The vast majority reported great dissatisfaction with the level of relief afforded by currently available medications for treatment of the chronic symptoms of these diseases. Today's announcement represents an important milestone for OptiNose as a company, but more importantly we are excited at the prospect of helping to address an area with such significant unmet need."

NAVIGATE I is a randomized, double-blind, placebo-controlled trial that enrolled 323 patients with nasal polyps and associated nasal congestion from 6 countries, including the United States. The study was 24 weeks in duration, with subjects randomized to either placebo or one of three doses of OPN-375 for the first 16 weeks, and with all subjects receiving open-label OPN-375 for the following eight weeks. As with NAVIGATE II, in addition to the co-primary endpoints, the study also found that OPN-375 treatment demonstrated statistically significant improvement in the other defining symptoms of the disease (nasal drainage, sinus pain and pressure, and loss of sense of smell), and in multiple other measures.

"In light of these additional positive results, we feel we have what we need to begin preparing a New Drug Application for OPN-375 to submit to FDA," said Ramy Mahmoud, M.D., MPH, President and Chief Operating Officer of OptiNose. "Our ongoing clinical research program has sensitized our team to the often underappreciated magnitude of suffering from these conditions, the inadequacy of the treatment options currently available and the paucity of new treatments coming down the pike. We are optimistic that OPN-375, if approved, could be an important new treatment option."

"As a physician long practicing in this therapeutic area, I find today's results to be incredibly encouraging," said 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 (ARS), as well as a principal investigator in OPN -FLU-3204, another study in the clinical development program for OPN-375, "For the large population of patients who are dissatisfied with available treatments, these results suggest that OPN-375 could be an important new option. If this product is approved, I would consider it a valuable tool in treating my 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 both a targeted and a deeply distributed manner. Available data, including two published Phase II trials, suggest that OPN-375 has the potential to help satisfy a significant, currently unmet need for effective options in the treatment of serious chronic nasal inflammatory diseases like chronic rhinosinusitis with nasal polyps. A global late-phase clinical program (including the NAVIGATE I and II trials) 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 1,600 patients, is now largely complete. OptiNose is also working to assure that other critical enablers of future OPN-375 product success, including a launch-ready supply chain and other appropriate pre-commercial efforts, will be in place to bring the product to market immediately following regulatory approval.

About the NAVIGATE I & II Trials

Two global placebo-controlled studies, NAVIGATE I and II, have been conducted to help assess the safety and efficacy of OPN-375 in patients with bilateral nasal polyposis. The trials began enrolling patients in October 2013.

These two randomized, double-blind, parallel-group, multicenter studies were designed to help 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 at the highest dose to allow additional safety and efficacy assessment. Patients in these trials received 100, 200 or 400 µg doses of OPN-375 or placebo twice daily.

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 serve to target delivery of 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). 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.

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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