OptiNose Presents Data from Phase 3 Trials with Investigational Product Using Exhalation Delivery System Technology for Treatment in Patients with Chronic Rhinosinusitis (CRS) with and without Nasal Polyps

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Data from two Phase 3 trials were presented for the first time today at the American Rhinologic Society's Annual Meeting

Data show significant improvement in both subjective symptoms and objective signs of disease with use of the Exhalation Delivery System for Fluticasone (EDS-FLU) in the studied populations

Patients with nasal polyps at baseline experienced significant reduction in polyp grade

EDS-FLU treatment produced significant improvements in all of the four core symptoms of CRS, a broad range of objective and subjective outcome measures, and quality of life

SAN DIEGO — Sept. 16, 2016 —OptiNose, a privately held specialty biopharmaceutical company, today presented data from two phase 3 trials investigating the clinical efficacy and safety of the Company's novel Exhalation Delivery Systems (EDS) in patients with Chronic Rhinosinusitis (CRS) with and without nasal polyps (the former also referred to simply as "Nasal Polyposis"). The findings were presented at the American Rhinologic Society's Annual Meeting in San Diego, CA.

"We are thrilled to present Phase 3 data on the use of our fluticasone exhalation delivery system (EDS-FLU), which we believe can help to better treat this deeply underserved patient population," said Peter Miller, CEO, OptiNose. "Although almost everyone with this disease tries conventional nasal steroid sprays at some point, including in many instances before or after nasal surgery, many continue to suffer from chronic symptoms. Based on the Phase 3 data announced today, we are confident that EDS-FLU has potential to really help patients and we look forward to completing the next steps to make this important product available to doctors and patients, including filing of a new drug application with the FDA."

Findings presented today include:

- **NAVIGATE II:**
  - 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. Most patients (87%) had previously used intranasal corticosteroids.
  - EDS-FLU at doses of 93 µg, 186 µg, and 372 µg twice daily, statistically significantly reduced both of the co-primary endpoints of nasal congestion/obstruction (-0.59, -0.68, and -0.62, respectively , $P<0.001$ vs placebo for all comparisons) and endoscopically measured total polyp grade (-1.31, -1.22, and -1.41, $P<0.001$ vs placebo for all comparisons).
  - EDS-FLU treatment also resulted in significant improvements in multiple secondary endpoints, including all of the four core symptoms of CRS (congestion/obstruction, up to a mean of -0.68, P<0.001; facial pain and pressure, up to a mean of -0.51, P<0.001; rhinorrhea, up to a mean of -0.62, P<0.001; and loss of sense of smell, up to a mean of -0.28, P<0.01) and quality of life as measured by the SNOT-22, up to a mean -21.5, P<0.001. Up to 82% of patients reported "much" or "very much" improvement in the disease after 24 weeks of treatment on a global impression of change assessment.
  - Higher doses of EDS-FLU (186 µg and 372 µg) generally resulted in numerically greater effect on some endpoints.
  - Treatment with EDS-FLU was generally well tolerated. The most common adverse events were Epistaxis and Nasal Mucosal Disorder (eg erythema). One nasal septum perforation was observed in a patient with prior nasal septum surgery.

- **EXHANCE-12:**
  - EXHANCE-12 is a long-term (one year) open label study that enrolled 223 patients with chronic rhinosinusitis with or without nasal polyps from 21 centers in the United States. All subjects were instructed to use the EDS-FLU at a dose of 372 µg twice daily, and most (96%) reported having previously used currently available steroids.
  - The pattern of adverse events reported over one year of use was consistent with previous data. The most common adverse events were epistaxis and nasal mucosal disorder (eg erythema). Common adverse events were generally local in nature, tended to be mild in severity, and were largely transient. Adverse events did not increase in frequency or severity with increasing duration or exposure to study drug.
  - Subjects were found to have improvement on subjectively reported measures of symptoms, including on the Sinonasal Outcomes Test (22-item) where mean improvement was 19.3 points, and on endoscopically assessed scores for change in local signs of disease, including nasal edema. Most patients (72%) reported their symptoms being "much" or "very much" improved on a global impression of change assessment.
  - Among patients with nasal polyps at baseline, treatment was accompanied by reductions in polyp grade through one year of follow-up and 54% of patients were observed to have a polyp grade of zero (no polyps visible) in at least one nostril after 12-mo of therapy.

"Data suggests that there may be tens of millions of people in the U.S. with symptoms of CRS. This condition is not allergic rhinitis, and many of these patients still report symptoms despite the availability of current treatments. Today's intranasal corticosteroids, a category including drugs like Flonase or Nasonex, use conventional nasal sprays to deliver the medicine and are considered first line therapy in published treatment guidelines; however, a substantial burden of unmet need still exists for many patients. The data presented today are exciting because they suggest that the new Exhalation Delivery System may become a valuable addition to currently available treatment alternatives," said Ramy Mahmoud, MD, MPH, President of OptiNose. "Exhalation Delivery Systems are intended to deliver medicine high and deep in the nose. Fluticasone is the most widely used nasal steroid today, and we are hopeful that a product using a new Exhalation Delivery System to deliver such a well-established medicine will earn a place in the future standard of care."

About OptiNose

OptiNose is a Specialty Pharmaceutical Company developing a promising pipeline of late stage new products. The Company's patented bi-directional Breath Powered® exhalation delivery technology platform is designed to create differentiated treatments by enabling high and deep intranasal drug deposition. OptiNose successfully out-licensed a first product at the end of phase 3 (Onzetra™ Xsail™, licensed to Avanir in North America, since acquired by Otsuka Pharmaceutical Co), and has reported clinical success with other products, including the EDS-FLU (OPN-375), an investigational treatment in development for chronic nasal inflammatory diseases which has completed Phase 3 in subjects with nasal polyposis. Other OptiNose pipeline products also target large markets with significant unmet need, including nose-to-brain technology applications such as OPN-300 for Autism. OptiNose has corporate offices in the US, Norway and the UK.

About OptiNose's Closed Palate Bi-Directional™ Breath Powered® Exhalation Delivery Technology

OptiNose's patented closed-palate bi-directional Breath Powered exhalation delivery technology is unique in that it uses the natural functions of a user's breath to propel medications beyond the nasal valve into deep, targeted areas of the nasal cavity, working differently than conventional nasal sprays. A user exhales into the device, creating a natural closure of 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 specially shaped sealing nosepiece. Narrow nasal passages are gently expanded and medication is transported beyond the nasal valve to targeted sites. After passing through the targeted regions, the exhaled air balances the pressure across the soft palate and opens a passage so that it can flow around to the opposite side of the nasal cavity and exit through the other side of the nose, rather than into the throat or lungs.

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