

## **OptiNose Announces FDA Acceptance for Filing of the New Drug Application for OPN-375**

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*FDA sets user fee goal date in September, 2017*

**YARDLEY, PA, January 31, 2017** – OptiNose™ today announced the U.S. Food and Drug Administration (FDA) has accepted for review the company's New Drug Application (NDA) for the investigational new product OPN-375. OptiNose is seeking marketing approval of OPN-375 in the U.S. for the treatment of nasal polyposis in adults. Under the Prescription Drug User Fee Act (PDUFA), a decision on the application is anticipated in September, 2017.

"The FDA acceptance of the new drug application for OPN-375 is a particularly exciting milestone for our company because OPN-375 represents the first step on our path towards becoming a leading ENT / Allergy specialty company," said Peter Miller, CEO of OptiNose. "The 2016 FDA approval of the first product we developed using our proprietary Exhalation Delivery System (EDS) technology gives us more confidence that our second EDS product, OPN-375, can be approved in 2017."

The NDA for OPN-375 includes data from more than 1,500 patients and includes two global Phase 3 dose-ranging pivotal efficacy trials, NAVIGATE I and NAVIGATE II, which evaluated the safety and efficacy of OPN-375 compared to placebo in the treatment of adults with bilateral nasal polyposis, two phase 3 open-label clinical trials in adults with symptoms of chronic sinusitis with and without nasal polyps (EXHANCE-3 and EXHANCE-12), and a comparative bioavailability study.

"We believe there is a great deal of dissatisfaction with the current clinical options for these patients, and that OPN-375 could be a valuable new treatment option," said Ramy Mahmoud, MD, MPH, President and COO of OptiNose. "Our team is eager for the opportunity to make this new product available to patients if it is approved, and we are already taking the necessary steps to make it happen."

### **About OptiNose™**

OptiNose is a commercial stage ENT / Allergy Specialty Biopharmaceutical Company on a mission to improve lives. The Company's first technology platform involves a patented closed-palate Breath Powered® technology used to develop Exhalation Delivery Systems (EDS) that produce high and deep intranasal deposition of medication. These exhalation delivery systems enable creation of products with the potential for meaningful new clinical benefits. OptiNose developed and out-licensed its first product at the end of phase 3 (Onzetra™ Xsail™ (sumatriptan nasal powder), licensed to Avanir Pharmaceuticals, Inc. in North America, since acquired by Otsuka Pharmaceutical Co., Ltd.). Onzetra Xsail received FDA approval in January 2016 and was launched in the U.S. in May 2016. The Company's second product candidate, an Exhalation Delivery System with fluticasone propionate (OPN-375) is being developed for treatment of nasal polyposis and chronic sinusitis. An NDA seeking marketing approval for the treatment of nasal polyposis was submitted in November 2016. Subsequent OptiNose pipeline products will aim to serve the needs of patients treated by ENT and allergy specialists. The Company is also engaged in early development work on products for neurologic orphan diseases where the "nose-to-brain" application of our technology may enable improved treatment. This includes OPN-300 (Prader-Willi Syndrome, Autism, others) and OPN-21 (narcolepsy and others). OptiNose has corporate offices in the US, UK and Norway.

### **Forward Looking Statements**

This press release may contain forward looking statements. Forward looking statements include statements about our future plans and may be indicated by words such as, "we anticipate," "we plan," or other similar words. While these forward-looking statements represent our current judgment on what the future holds, they are subject to risks and uncertainties that could cause actual results to differ materially. You are cautioned not to place undue reliance on these forward-looking statements, which reflect our opinions only as of the date of this presentation. We are not obligating

ourselves to revise or publicly release the results of any revision to these forward looking statements in light of new information or future events.

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