OptiNose Announces FDA Approval for ONZETRA™ Xsail™ (sumatriptan nasal powder), a New Treatment for Acute Migraine Using Bi-Directional™ Breath Powered® Technology

January 28, 2016 10:56 AM ET

Product expected to be available in the U.S. in coming months

YARDLEY, PA, January 28, 2016— OptiNose, a privately-held specialty biopharmaceutical company, today announced that its licensing partner, Avanir Pharmaceuticals, Inc. has reported that the U.S. Food & Drug Administration (FDA) approved ONZETRA™ Xsail™ (sumatriptan nasal powder), formerly AVP-825, for the acute treatment of migraine with or without aura in adults (see Full Prescribing Information and Limitations of Use at www.ONZETRA.com). ONZETRA Xsail is the first product developed by OptiNose to receive FDA approval and is an intranasal medication delivery system using the novel Xsail Breath Powered Delivery Device. The Xsail device is based on OptiNose's unique and patented Bi-Directional Breath Powered technology platform and delivers a low dose of sumatriptan powder into the nose in a new and different way.

"Our whole team is pleased and excited about this approval and about the opportunity to see migraine patients benefit from using a product based on our Bi-Directional Breath Powered technology platform," said Ramy Mahmoud, MD, MPH, President of OptiNose. "This approval highlights the ability of OptiNose to successfully bring differentiated new products that use our innovative technology to the market. We love the idea of helping people, and our team is working hard to create even more new treatments to do just that."

"Many patients report that they are not fully satisfied with currently available migraine treatments, and ONZETRA Xsail will provide physicians and patients with a new alternative that offers relief in an innovative way–by using an exhaler," commented Stephen Silberstein, MD, Neurologist at the Headache Center, Thomas Jefferson University Hospital in Philadelphia, PA, Past President of the American Headache Society and a Principal Investigator in the OptiNose clinical development program for ONZETRA Xsail. "The design of the Xsail Breath Powered Delivery Device harnesses the patient's own breath to seal off the nose from the throat and deliver a low dose of a trusted medication to the richly vascular passages deep in the nose. It's an alternate approach to treating migraines that is both unique and effective."

After completing Phase III development, OptiNose out-licensed the North American commercialization and further development rights for ONZETRA Xsail to Avanir Pharmaceuticals, Inc. (a subsidiary of Otsuka America, Inc.). Under the terms of the licensing agreement, OptiNose receives upfront and milestone payments collectively valued at up to $110 million and tiered double digit royalty payments based on net sales.

"In addition to making an important treatment option available to a suffering patient population, the approval of ONZETRA Xsail also provides OptiNose the ability to use the licensing proceeds to help with the research, development, and future commercialization of our next product candidate, OPN-375," noted Peter Miller, Chief Executive Officer of OptiNose. "If approved, we believe that OPN-375, which is a late phase pipeline asset, may play a valuable role in helping to treat patients for indications associated with chronic nasal inflammatory disease, such as nasal polyposis and chronic sinusitis. The proceeds will also help us pursue other pipeline assets in 2016."

Important Safety Information

ONZETRA Xsail is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use

- Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with ONZETRA Xsail, reconsider the diagnosis of migraine before treatment of subsequent attacks with ONZETRA Xsail

- *ONZETRA Xsail is not indicated for the prevention of migraine attacks*
- Safety and effectiveness of ONZETRA Xsail have not been established for the treatment of cluster headache

ONZETRA is contraindicated in patients with:

- Ischemic coronary artery disease (CAD) or coronary artery vasospasm, including Prinzmetal's angina; or Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders
- History of stroke, transient ischemic attack (TIA), or history of hemiplegic or basilar migraine; peripheral vascular disease; ischemic bowel disease; or uncontrolled hypertension
- Recent (i.e., within 24 hours) use of ergotamine-containing or ergot-type medication, or another 5-HT_1 agonist; or concurrent or recent (within 2 weeks) use of a MAO-A inhibitor
- Known hypersensitivity to sumatriptan (angioedema and anaphylaxis seen) or severe hepatic impairmentIn clinical trials, the most common adverse reactions (≥ 2% and > placebo) were abnormal taste, nasal discomfort, rhinorrhea, and rhinitisFor additional important safety information about ONZETRA, please see full Prescribing Information.
- Advise patients to carefully read the Patient Information and Instructions for Use prior to using ONZETRA.
- Other serious adverse events associated with the use of sumatriptan or 5-HT_1 agonists include: myocardial ischemia/infarction, Prinzmetal's angina, arrhythmias; chest, throat, neck and/or jaw pain/tightness/pressure; cerebral hemorrhage, subarachnoid hemorrhage, and stroke; peripheral vascular ischemia, gastrointestinal vascular ischemia/infarction, and Raynaud's syndrome, medication overuse headache; serotonin syndrome; significant elevation in blood pressure; anaphylactic/anaphylactoid reactions; and seizures.

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 exhaler 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 OptiNose

"OptiNose" as used above refers to OptiNose, Inc. and its wholly owned subsidiaries, as applicable. 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, ONZETRA™ Xsail™ (formerly AVP-825), to Avanir Pharmaceuticals, Inc. (now a subsidiary of Otsuka America, Inc.) in North America, and has reported clinical success with other product candidates, including OPN-375, a treatment in development for Chronic Nasal Inflammatory Diseases. Other OptiNose pipeline product candidates 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.

Forward Looking Statements

In addition to historical facts or statements of current condition, this press release may contain forward looking

statements, which may provide OptiNose's current expectations or forecasts of future events or statements about future plans, including with regard to anticipated scientific progress on its research programs, development of potential pharmaceutical products, interpretation of clinical results, prospects for regulatory approval, manufacturing development and capabilities, market prospects for its products, sales and earnings guidance, and other statements regarding matters that are not historical facts. OptiNose's performance and financial results could differ materially from those reflected in these forward-looking statements due to general financial, economic, regulatory and political conditions affecting the biotechnology and pharmaceutical industries as well as more specific risks and from time to time. Given these risks and uncertainties, any or all of these forward-looking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. Furthermore, OptiNose does not intend to update publicly any forward-looking statement, except as required by law. The Private Securities Litigation Reform Act of 1995 permits this discussion.

This press release may also contain statements, opinions, assumptions, summaries of study results or characterizations that are projections or aspirational in nature, that have not been reviewed and/or approved by the Food and Drug Administration (FDA), Patent and Trademark Office (PTO) or other applicable governmental or regulatory bodies. Moreover, some or all of these statements have not been evaluated by FDA in connection with a regulatory review of the OptiNose Products OPN-375 and OPN-300 and you are advised that these are investigational products that have not been approved by any regulatory authority.

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