St. Renatus, LLC

FOR IMMEDIATE RELEASE

For More Information, Contact:

Jennifer Umland
Media Relations
970-282-0156 ext. 3517
jumland@st-renatus.com

St. Renatus, LLC Announces FDA Approval of KOVANAZE™ (tetracaine HCl and oxymetazoline HCl) Nasal Spray for Use in Dentistry

July 12, 2016 - St. Renatus LLC, a privately held company based in Fort Collins, Colorado, is pleased to announce it received U.S. Food and Drug Administration (FDA) approval on June 29, 2016 for its first product, a new dental anesthetic, KOVANAZE™ (tetracaine HCl and oxymetazoline HCl) Nasal Spray. This is the first product that allows for dental anesthesia to be administered through a nasal spray without using a needle.

"For more than 100 years, the dental industry has delivered dental anesthesia using a needle injection. Now, through the efforts of a dedicated team, we have developed a revolutionary needle-free method for delivering pulpal anesthesia," said Steve Merrick, St. Renatus' CEO.

Kovanaze is intended for use in dentistry as a topical anesthetic, delivered in the nasal cavity to achieve pulpal (tooth nerve) anesthesia for the restorative treatment of teeth. Like traditional dental injections, this product delivers a local dental anesthetic but without the needle.

Kovanaze is indicated for regional anesthesia when performing a restorative procedure on Teeth 4-13 and A-J in adults and children who weigh 40 kg or more.

About St. Renatus
St. Renatus, LLC was founded to develop a revolutionary innovation—the world's first-known dental anesthetic administered through the nasal cavity, designed for use in procedures involving most of the upper teeth, with a goal of gaining FDA approval to commercialize and distribute. The company's name comes from the patron saint of anesthesia and has Latin roots meaning *new beginning*.

Learn more about St. Renatus by visiting www.st-renatus.com. Customer support line for Kovanaze: 1-800-770-9400.

###

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use KOVANAZE™ NASAL SPRAY safely and effectively. See the full package insert for prescribing information for KOVANAZE NASAL SPRAY.

KOVANAZE (tetracaine HCl and oxymetazoline HCl) Nasal Spray
Initial U.S. Approval: 2016

----------INDICATIONS AND USAGE----------

KOVANAZE contains tetracaine HCl, an ester local anesthetic, and oxymetazoline HCl, a vasoconstrictor. KOVANAZE is indicated for regional anesthesia when performing a restorative procedure on Teeth 4-13 and A-J in adults and children who weigh 40 kg or more.

----------DOSAGE AND ADMINISTRATION----------

KOVANAZE is for intranasal use only. Administer KOVANAZE ipsilateral (on the same side) to the maxillary tooth on which the dental procedure will be performed.

Age Group	Dose
Adults (≥ 18 years old)	2 sprays (0.2 mL per spray), 4 to 5 minutes apart
	1 additional spray (0.2 mL) if adequate anesthesia has not been achieved 10 minutes after the second spray
Children who weigh 40 kg or more	2 sprays (0.2 mL per spray), 4 to 5 minutes apart

----------DOSAGE FORMS AND STRENGTHS----------

Nasal spray in pre-filled, single-use sprayer: 6 mg tetracaine HCl and 0.1 mg oxymetazoline HCl (equivalent to 5.27 mg tetracaine and 0.088 mg oxymetazoline) in each 0.2 mL spray.

----------CONTRAINDICATIONS----------

Known hypersensitivity to tetracaine, benzyl alcohol, other ester local anesthetics, *p*-aminobenzoic acid (PABA), oxymetazoline, or any other component of the product.

----------WARNINGS AND PRECAUTIONS----------

Hypertension and Thyroid Disease: Shown to increase blood pressure in some clinical trial patients. Monitor blood pressure. Use in patients with inadequately controlled hypertension or active thyroid disease is not advised (5.1).

Epistaxis: Use is not recommended in patients with a history of frequent nose bleeds (≥5 per month). If a decision to use is made, monitor these patients carefully.

Dysphagia: Carefully monitor patients for dysphagia.

Methemoglobinemia: May cause methemoglobinemia, particularly when used with methemoglobin-inducing agents. Use in patients with history of congenital or idiopathic methemoglobinemia not advised. If central cyanosis unresponsive to oxygen therapy occurs, suspect methemoglobinemia, confirm diagnosis with co-oximetry, and treat with a standard clinical regimen.

Anaphylactic Reactions: Seek emergency help if an anaphylactic reaction occurs.

----------ADVERSE REACTIONS----------

The most common adverse reactions occurring in >10% of patients include rhinorrhea, nasal congestion, lacrimation increased, nasal discomfort, and oropharyngeal pain.

Transient, asymptomatic elevations in systolic blood pressure (≥ 25 mm Hg from baseline) and diastolic blood pressures (≥ 15 mm Hg from baseline) have been reported.

To report SUSPECTED ADVERSE REACTIONS, contact St. Renatus, LLC at 1-800-865-4925 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

Monoamine oxidase inhibitors (MAOIs): Concomitant use of MAOIs, nonselective beta adrenergic antagonists, or tricyclic antidepressants may cause hypertension and is not recommended.

Oxymetazoline-containing products: Discontinue use 24 hours prior to KOVANAZE administration.

Intranasal products: Avoid concomitant use.