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St. Renatus, LLC., with Guidance from the U.S. Food and Drug Administration, has Established Readiness to Proceed to Phase 3 Trials for a New Needle-Free Dental Anesthetic
Studies are Being Undertaken to Demonstrate that a Nasal Mist Topical Anesthetic Would Achieve Dental Anesthesia in the Maxillary Arch

FORT COLLINS, Colo. – March 7, 2011 – St. Renatus, LLC, the northern Colorado start-up Company dedicated to bringing to market a needle-free dental anesthetic, announced today that the company had a favorable End of Phase 2 review with the U.S. Food and Drug Administration (FDA), and agreed that in the near future, the company will proceed with conducting Phase 3 efficacy studies to determine the exact parameters for their nasal mist dental anesthetic achieving dental anesthesia in the maxillary arch.

St. Renatus and the FDA discussed details for both Phase 3 Adult and Pediatric studies to be conducted in the near future. Final revised protocols will be forwarded to the FDA in the coming weeks.

The Phase 2 clinical trial results submitted to the FDA indicated that the nasal mist is comparable to that of a standard needle-injected dental anesthetic.

“We are very pleased with how the nasal mist has performed in trials thus far, and with the outcome of our meetings with the FDA. We believe it represents a significant step forward for both St. Renatus and the field of Dentistry,” said Steve Merrick, Chief Executive Officer for St. Renatus, LLC.

Initial consumer research for the nasal mist product found that if patients are given the choice between a nasal mist anesthetic and a needle-injected anesthetic, 90 percent of all patients are very or somewhat likely to choose the new product, and 23 percent are very likely to switch to a dentist offering the nasal spray option.¹

96% of dentists surveyed expect to offer the new nasal mist anesthetic to their patients.¹

Phase 3 clinical studies required by the FDA are expected to be completed in the second half of 2011. A New Drug Application will likely be filed in the latter part of 2011.

ABOUT ST. RENATUS

St. Renatus, LLC was founded to commercialize and distribute a new needle-free dental anesthetic in the form of a nasal mist that is designed to achieve dental anesthesia in the maxillary arch. St. Renatus aims to create a better experience for dentists and qualifying patients by conducting clinical trials on an accurate and sophisticated method to anesthetize the upper teeth without the risk and pain of a needle. For more information, please visit www.st-renatus.com or call 970.282.0156.

References:

- 1. Research conducted by Industrial Research Center, Glen Mills, PA. February, 2011.*

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