Intranasal Therapeutics, Inc.
Comfort. Convenience. Control.

New ITI Study Shows Potential of Intranasal Midazolam as an Effective, Noninvasive Sedative

Lexington, Ky., July 25, 2006 – Intranasal Therapeutics, Inc. (ITI) announced today that a proof-of-principle study published in the August issue of the peer-reviewed journal *Anesthesia & Analgesia* demonstrates the potential of intranasally delivered midazolam as a convenient, fast-acting and noninvasive alternative to intravenous and oral forms of this widely used sedative.

"Our preliminary study in 12 healthy volunteers clearly demonstrates that this novel intranasal formulation of midazolam is rapidly and reliably absorbed," said Daniel P. Wermeling, Pharm.D., Associate Professor, College of Pharmacy at the University of Kentucky, and ITI's Chief Scientific Officer. "If further studies confirm our findings, the new formulation could be developed as a viable therapeutic alternative to injectable and oral dosage forms for relieving preprocedure anxiety in adults and children."

Approximately 100 million procedures are performed each year that require treatment for anxiety prior to surgery and other medical and dental procedures. Sedatives in the form of oral tablets, syrup and intramuscular options have clinical limitations, however, and no nasal alternative currently is available. ITI therefore is developing intranasal midazolam for sedation, amnesia and anxiety relief prior to or during medical procedures. An additional Phase I clinical study has been completed, and follow-up pharmacokinetic studies are in development.

The study entitled "Pharmacokinetics and Pharmacodynamics of a New Intranasal Midazolam Formulation in Healthy Volunteers" compared 5 mg of midazolam delivered to 12 healthy volunteers via intravenous, intramuscular and intranasal administration. Findings demonstrated that the intranasal dose was well absorbed very rapidly, i.e. in less than 10 minutes with 72 percent bioavailability. In addition, the intranasal dose demonstrated rapid onset and short duration of action, and its sedative effects were more similar to intravenous than to intramuscular administration.

The intranasal midazolam is also a sterile product, eliminating the use of potentially irritating antimicrobial preservatives; all subjects completed the study without clinically significant or serious adverse events.

Midazolam, like other benzodiazepines, is heat labile and cannot withstand terminal sterilization. ITI's unique aseptic nasal filling and manufacturing capability enables the production of benzodiazepines as well as protein and peptide nasal sprays. This capability was reported recently by *In-PharmaTechnologist* in an article entitled "Aseptic nasal spray manufacturing an untapped market." ITI continues its market leadership in aseptic, preservative-free nasal product development.

The midazolam study was conducted for ITI by investigators at the University of Kentucky's College of Pharmacy and Division of Otolaryngology – Head & Neck Surgery, A. B. Chandler Medical Center. The abstract may be viewed at http://www.anesthesia-analgesia.org/cgi/content/abstract/103/2/344 . Additional publications involving ITI's product candidates can be found at: http://www.intranasal.com/publications.html .

About ITI

Intranasal Therapeutics, Inc. (ITI) is a specialty pharmaceutical company focused on developing innovative nasally delivered pharmaceutical products, with a particular focus on drugs to treat pain and central nervous system disorders for which there is proven, unsatisfied consumer need. The Company currently has four products in its clinical development pipeline, with several others in formulation or preclinical development. ITI's goal is to become a leader in the field of intranasal pharmaceuticals by applying formulation expertise across a broad range of therapeutic areas to create new and differentiated products that improve safety, efficacy and convenience for patients, caregivers and health care professionals.

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