

# FDA Approves Needle-Free Pain Drug

SOUTH SAN FRANCISCO, Calif., Aug 17, 2007

Anesiva, Inc. (Nasdaq: ANSV) announced today that the U.S. Food and Drug Administration (FDA) has approved Zingo™ (lidocaine hydrochloride monohydrate) powder intradermal injection system, which provides rapid, topical, local analgesia to reduce the pain associated with venous access procedures, such as IV insertions or blood draws, in children ages three to 18. Zingo™ is an easy-to-administer, single-use, needle-free system containing 0.5 mg sterile lidocaine powder. It provides a rapid onset of action, allowing intravenous line placement or venipuncture to begin one to three minutes after administration.

"Blood draws and IV insertions are the most frequently reported painful events in hospitalized children. Despite guidelines recommending the use of topical anesthetics prior to venous access procedures, currently available local anesthetics commonly take 20 minutes or longer to act, making their use in today's fast-paced hospital environment difficult. FDA approval of Zingo™ provides a unique option for healthcare providers who strive to safely and effectively manage children's pain during these procedures," said John P. McLaughlin, chief executive officer of Anesiva. "Anesiva is committed to improving pain management, and the approval of Zingo™ marks an important step toward reaching this goal. This favorable decision by the FDA to approve Zingo™ came more than five weeks earlier than our PDUFA date of September 24th, and we are grateful for the efforts put in by the agency and for the cooperative relationship that we enjoyed during this process."

Guidelines and recommendations from the American Academy of Pediatrics, the American Pain Society and the Infusion Nurses Society all call for the use of topical anesthetics prior to venous access procedures.

"Healthcare providers have always faced an uncomfortable trade-off when it comes to the use of topical anesthetics: they can choose speed and convenience or patient comfort," said William T. Zempsky, M.D., associate professor, Department of Pediatrics, University of Connecticut; associate director, Pain Relief Program, Connecticut Children's Medical Center, Hartford, who led the pediatric clinical trials of Zingo™. "With

Zingo™, doctors and nurses can offer the best of both worlds, providing pain control that won't slow the delivery of medical care."

Data from two pivotal, placebo-controlled, Phase 3 clinical studies, which collectively enrolled 1,109 patients across 15 U.S. clinical centers, demonstrated that Zingo™, a preparation of powdered lidocaine administered through a needle-free, pre-filled, disposable device, provided statistically significant pain relief in children ages three to 18 undergoing venous access procedures, such as IV line placements. These data indicated that treatment with Zingo™ quickly and effectively reduced pain when given just one to three minutes prior to the venous access procedure. Zingo™ was well-tolerated. The most common adverse reactions were redness (erythema), red dots (petechiae) and swelling (edema) at the site of administration.

Venous access procedures, like IV insertions and blood draws, are among the most common interventions performed at a hospital, with more than 18 million pediatric venous access procedures and 400 million total procedures per year in the U.S. Needlesticks are also a source of deep anxiety. An Impulse Research survey conducted last year by Anesiva found that 70 percent of children experience fear and stress during a visit to the doctor or hospital that involves a needlestick procedure, and more than half of all children -- even those older than seven -- cry during these procedures. The problem is compounded in children with chronic illnesses who must undergo frequent IV insertions.

"Pre-treating pain associated with venous access procedures is the right thing to do, and parents should feel comfortable asking how pain can be minimized for their child," said Micke A. Brown, BSN, RN, director of advocacy, American Pain Foundation. "Regular use of topical anesthetics to lessen a painful needlestick can be a nurse's best friend. It allows us to quickly gain patient trust and sets a therapeutic tone that positively affects the hospital experience."

Anesiva will provide updated information on the commercialization plan for Zingo™ in the coming weeks. In addition, Anesiva is now studying Zingo™ in a large Phase 3 trial in adults. The company will use the data generated in that trial as the basis for an FDA filing to expand the label to include adults.

There may be opportunities to use the needle-free delivery technology employed in Zingo™ for the delivery of drugs other than lidocaine. Possible drug candidates include

insulin, human growth hormone, erythropoietin, calcitonin, and other medications, excluding vaccines. The company may license the rights to the use of this technology for such other medications to third parties.

### **About Zingo™**

Zingo™ is a ready-to-use, single-use, needle-free system that delivers sterile lidocaine powder into the epidermis of the skin and provides topical, local analgesia in one to three minutes after administration. This rapid onset, which may be especially useful in pediatric populations and busy emergency room settings, means the product can be incorporated into a medical procedure allowing uninterrupted care, an important advantage over current options. In addition to the hospital setting, Zingo™ may be used in physicians' offices and clinical laboratories.

Source: Anesiva