

Fuisz Pharma LLC Announces New Patent Allowance for Its Helicopter(TM) Tablet Shape With Improved Swallowability; Adds to Existing Tablet Shape Patent Estate

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MIAMI, Jan. 20, 2015 (GLOBE NEWSWIRE) -- Fuisz Pharma LLC announced today that it has received a notice of allowance from the United States Patent and Trademark Office in connection with its utility patent application entitled "Solid Dosage Form That Promotes Reliable Oral, Esophageal and GI Transit" (Application No. 13/759,138). The allowed claims cover certain tablet and caplet designs for improved swallowability, including the tablet that Fuisz Pharma calls the "Helicopter™". The Helicopter™ shape has been demonstrated through in vivo clinical trials to enable easier swallowing and more reliable, faster esophageal clearance as compared with conventional tablet shapes.

Joseph Fuisz, Managing Member, stated, "The allowance of patent claims around our Helicopter™ shape further bolsters our tablet shape portfolio, which previously saw the issuance of US 8,383,135 which covers our 'Saturn™' tablet shape."

"We are pleased that the United States Food and Drug Administration has recently come to recognize the therapeutic criticality of esophageal transit, the role of dosage form shape in esophageal transit, and the necessity of generic products following the innovator shape (<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm377938.pdf>)."

"The Helicopter™ and Saturn™ tablets offer a great benefit through faster and more reliable esophageal transit. The high frequency of esophageal transit failure is increasingly understood by physicians and regulators. Moreover, the range of drug classes that provoke esophageal irritation extends far beyond the bisphosphonates demonstrated by the FDA's adverse event reporting system. Such classes include common drugs like cox-2's, statins and NSAID's. Moreover, esophageal transit failure results in delayed C(max) – with studies demonstrating C(max) in supine patients with an average C(max) delay of seventy minutes. This delay may be critical particularly where the drug dosage meets a time sensitive patient need."

Dr. Richard Fuisz, Founding Member of Fuisz Pharma (http://en.wikipedia.org/wiki/Richard_Fuisz), commented, "This is an exciting innovation that addresses a long-standing need that has finally come into the focus of regulators. However, the pharmaceutical industry has been slow to progress on the very real role of conventional shapes in causing swallowing and very real esophageal transit issues that sometimes result in excoriation to patients. This is not limited to osteoporotic medications, but can include doxycycline, aspirin, iron supplements, ibuprofen, naproxen and the list goes on. It is my personal opinion that this shape issue should be appreciated by the industry before it is forced on it by lawyers."

Dr. Fuisz continued: "This patent allowance and the underlying invention enable a therapeutically superior product

with robust, fresh patent protection. Yet, the adoption of Saturn™ or Helicopter™ will require no formulation change and offers a quick regulatory path. Thus, the Helicopter™ Saturn™ offers a compelling therapeutic proposition for providers and a strong value proposition for industry adoption."

Fuisz Pharma is a private pharmaceutical technology company originated by the Fuiszes. The Fuiszes have made substantial contributions in drug delivery including orally dissolving tablets and novel particle coating systems at Fuisz Technologies; inventing and developing thin film drug delivery technologies at Kosmos Pharma and MonoSol Rx, as well as independently developing extruded sheet technology, and have extensive experience working with big and specialty pharma. Fuisz Pharma is also active in diagnostic systems. Fuisz Pharma has its headquarters in Miami. www.fuisz.com.

Joseph Fuisz
202 669 5097

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Corporate Headquarters

5200 W. Century Blvd.
Suite 890
Los Angeles, CA 90045
Phone: (800) 307-6627
Fax: (800) 307-3567

European Headquarters

Nikolaj Plads 6
P.O. Box 1040
Copenhagen, Denmark
Phone: +45 33 77 03 77
Fax: +45 33 12 86 13