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## Fuisz Pharma Announces Patent Allowance For New Tablet And Caplet Shapes That Promote Rapid, Reliable Esophageal Transit



MIAMI, Jan. 23, 2013 /PRNewswire/ -- 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" (US 20120141545). The allowed claims cover Fuisz Pharma's new tablet and caplet designs for improved transit, including the tablet that Fuisz Pharma calls the "Saturn™". The Saturn™ has been demonstrated through in vitro tests and in vivo clinical trials to enable easier swallowing and more reliable, faster esophageal clearance as compared with conventional tablet shapes. A photo of the Saturn™ is included below.



(Photo: <http://photos.prnewswire.com/prnh/20130123/PH46501>)

Joseph Fuisz, Managing Member, stated, "This allowance of patent claims around our Saturn™ tablet has important therapeutic and commercial implications."

The Saturn™ tablet offers a great benefit through its faster and more reliable esophageal transit. The high frequency of esophageal transit failure is increasingly understood. Moreover, the breadth of drug classes that provoke esophageal irritation is increasingly understood to extend far beyond the bisphosphonates as is manifest from the FDA's adverse event reporting system, including cox-2, statins and NSAIDs. Moreover, esophageal transit failure results in delayed C(max) – with one published study showing C(max) in supine patients with an average C(max) delay of seventy minutes.

Importantly for Fuisz Pharma, the FDA is increasingly recognizing the role of tablet shape in esophageal transit with a view towards requiring generics to follow the size and shape of the reference, branded product.

This patent allowance and the underlying invention can enable a therapeutically superior product with robust, fresh patent protection. Yet, the adoption of Saturn™ will generally require no formulation change and offers a concise, clear regulatory path (through post approval supplement 21 CFR 314.70 and 314.71). The Saturn™ is simply made using a new tablet die which Fuisz has already vetted. Thus, the Saturn™ offers a compelling proposition for industry adoption."

Dr. Richard Fuisz, Founding Member of Fuisz Pharma ([http://en.wikipedia.org/wiki/Richard\\_Fuisz](http://en.wikipedia.org/wiki/Richard_Fuisz)), commented, "I am personally very proud, with my son Joseph, of this invention. There are many reasons for that pride. Firstly, the product makes possible a dramatic improvement in health care. You must get the dosage unit to its effective site in order to get proper blood levels. The most sophisticated pharmacology and the most sophisticated analytical methods, are meaningless if the drug does not pass to its absorptive site. Secondly, at age 73, I am proud to once again prove that it is the focus and perseverance of the individual that makes progress. Often forgotten in an era when success is, too often by the younger generation, thought to be synonymous with big venture capital and large, filled parking lots. If you are a small inventor reading this: take heart, you may well have the advantage."

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 and is not affiliated with MonoSol Rx. [www.fuisz.com](http://www.fuisz.com).

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