

August 22, 2011

[Mitsubishi Tanabe Pharma Corporation](#)

## **Mitsubishi Tanabe Pharma Prevails in U.S. Argatroban Patent Litigation**

**Osaka, Japan August 22, 2011** – Mitsubishi Tanabe Pharma Corporation (President & CEO: Michihiro Tsuchiya) announced today that the U.S. Court of Appeals for the Federal Circuit (“CAFC”) has upheld the validity and enforceability of U.S. Patent covering the formulation of Argatroban (“Formulation Patent”) on August 2, 2011.

The CAFC ruling affirmed the June 2010 decision upholding the Formulation Patent’s validity by the U.S. District Court for the Southern District of New York in a lawsuit brought by Mitsubishi Tanabe Pharma (licensee of the Formulation Patent) together with Mitsubishi Chemical Corporation (holder of the Formulation Patent), Encysive Pharmaceuticals, Inc. (holder of the new drug application for Argatroban), and GlaxoSmithKline (marketer of Argatroban in North America) against Barr Laboratories, Inc. and Pliva-Hrvatska D.O.O. (collectively, “Barr”).

As the result of this decision rendered by the CAFC, the US Food and Drug Administration is prohibited from giving final approval for Argatroban under Barr’s abbreviated new drug application until June 30, 2014 (expiration date of the Formulation Patent), therefore Barr is unable to market Argatroban in the US until then.

Argatroban, the world’s first selective antithrombin product, entered into the US market for the treatment for heparin-induced thrombocytopenia (“HIT”) in 2000, and in Europe, Canada and Japan thereafter for the treatment for HIT and now has become the world’s standard product for the treatment for HIT.

Mitsubishi Tanabe Pharma sees intellectual property as one of its most important resources, and intends to take appropriate legal actions against infringements or the risk of infringement of our intellectual property in the future.

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