

September 30, 2013

Press release:

Mitsubishi Tanabe Pharma Corporation

**Regarding Administrative Action Related to  
Violation of Pharmaceutical Affairs Law of Japan**

Osaka, Japan, September 30, 2013---Today, Mitsubishi Tanabe Pharma Corporation and its subsidiary Bipha Corporation (1007-124, Izumisawa, Chitose, Hokkaido), received administrative actions issued by the Minister of Health, Labour and Welfare. These administrative actions were issued in regard to a violation of the Pharmaceutical Affairs Law of Japan related to Medway Injection 5% and Medway Injection 25%, which are recombinant human serum albumin products. Bipha was issued a suspension order for its pharmaceutical manufacturing operation from October 2, 2013 to October 31, 2013, as well as a business improvement order. Mitsubishi Tanabe Pharma was issued a business improvement order. Bipha and Mitsubishi Tanabe Pharma are taking these administrative actions very seriously, and we offer our sincere apologies.

These actions were issued due to the manufacture and sale of products that contained Pluronic F68, an ingredient that is not listed in the approval documentation, during the period in which Medway Injection 5% and Medway Injection 25% were manufactured and sold, from May 2008 to March 2009. As a manufacturer, Bipha manufactured products containing Pluronic f68. As a manufacturer and seller, Mitsubishi Tanabe Pharma manufactured and sold such products.

In March 2009, Mitsubishi Tanabe Pharma implemented a voluntary recall of all of these products that were already in distribution channels, and halted sales. Currently, these products are not being distributed. In addition, during the period in which these products were being sold, no reports of health problems resulting from these products were received.

An administrative action regarding the approval, manufacturing control, and quality control for these products was received in April 2010. Since that time, Mitsubishi Tanabe Pharma and all Group companies have worked to implement business improvement initiatives. This recent incident regarding the use of Pluronic f68 was confirmed through an in-house investigation that arose in relation to whistle-blowing regarding these business improvement initiatives.

The Mitsubishi Tanabe Pharma Group has implemented rigorous business improvement initiatives to restore the trust of society. Once again, the Group will do its utmost to prevent a recurrence and ensure compliance and to regain the trust of patients, medical professionals, and the rest of society.

The Company has no plan to revise the current consolidated financial forecasts by this incident.

**About Pluronic f68**

Pluronic f68 is a nonionic polymer surfactant. It is listed in the standard of Japan's pharmaceutical additives regulations, and it has been used as an ethical pharmaceutical additive and as an ethical pharmaceutical.

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