March 24, 2009
Mitsubishi Tanabe Pharma Corporation

Withdrawal of Marketing Authorization for Recombinant Human Serum Albumin Preparation "Medway Injection 5%" and Voluntary Recall of "Medway Injection 5%" and "Medway Injection 25%"

Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka, President: Natsuki Hayama) announces that the company decided to withdraw the marketing authorization for the recombinant human serum albumin preparation "Medway Injection 5%"[*1] and to voluntarily recall "Medway Injection 5%" and "Medway Injection 25%"[*1] from the market, which have been developed by the company jointly with the consolidate subsidiary Bipha Corporation (Head Office: Chitose, Hokkaido, President: Yoshihiko Gion) and manufactured and distributed by the company.

Marketing of "Medway Injection 5%" and "Medway Injection 25%" as recombinant human serum albumin preparations for therapeutic use were authorized in October 2007 and these two products were launched on the Japanese market in last May.
At the end of last year, Bipha Corporation reported to the company that Bipha had intentionally exchanged some of the authentic test data with irrelevant data when preparing the data package submitted with the application for approval of partial modification of the once issued approval (hereinafter called "application for partial modification") to enable extension of the shelf life of "Medway Injection 5%."
Because this fact was confirmed by our follow-up study, we canceled the application for partial modification on January 26, 2009. At the same time, detailed investigations were conducted, covering other tests on the product as well, at Bipha Corporation and the company, revealing that exchange of test data had been conducted on the PCA reaction test in rats[*4] carried out in 2005 for validation of commercial scale production[*3] within the framework of GMP Inspection concerning Pharmaceuticals[*2] for acquisition of marketing authorization of "Medway Injection 5%." The company has therefore decided to withdraw the marketing authorization on this product and to recall the product voluntarily from the market.
Regarding "Medway Injection 25%" we have identified no such fraudulent act. However, considering that the validation of commercial scale production on "Medway Injection 25%" was carried out at the same manufacturing plant and during the same period as those for "Medway Injection 5%," we have decided to recall also this product voluntarily.

The "Medway Injection 5%" manufactured during the said validation for commercial scale production was not distributed to the market, and we have confirmed that the "Medway Injection 5%" and "Medway Injection 25%" distributed after the start of marketing satisfy the current standards and specifications, without any quality problem. We have received no report on health hazards arising from the use of any of these products.
During the series of investigations conducted within the company, departure of some tests from the standard operating procedure was detected, but we have confirmed that such departure does not adversely affect the quality of the products. At the same time,

we have taken actions to correct the relevant testing methods.

Mitsubishi Tanabe Pharma, as a pharmaceutical enterprise involved in life-related industry, is seriously concerned with the fact mentioned above and expresses its sincere apology to patients and medical professionals. We will identify the causes for this event and take actions to resolve the problems identified. In addition, we will ensure complete compliance with GMP, reliability of data packages submitted with application for approval and thorough compliance with pharmaceutical regulations across the company and member companies of our group, with a goal of preventing recurrence of this kind of event.

Voluntary recall pertains to the following products.

Product	Specifications	Lot No.	Expiry date
Medway Injection 5%	250 mL/bottle	Q001L	March 2009
		Q002L	August 2009
		R003L	December 2009
		R003LT	December 2009
Medway Injection 25%	50 mL/bottle	Q001S	January 2010
		Q002S	January 2010
		Q003S	February 2010
		Q004S	February 2010
		Q005S	May 2010
		Q006S	September 2010
		Q007S	September 2010
		Q008S	October 2010
		Q008ST	October 2010

<Remarks>

(*1) ”Medway Injection”

“Medway Injection” is a preparation of recombinant human serum albumin (rHSA) produced by *Pichia pastoris* transfected with a gene encoding human serum albumin (HSA). It was marketed in May 2008.

Medway Injection 5% and 25% preparations have been manufactured in an integrated manner at Bipha Corporation located in Chitose, Hokkaido, a subsidiary of Mitsubishi Tanabe Pharma Corporation as 5% and 25% human serum albumin preparations produced by biotechnology (genetic recombination with yeast serving as the host).

Because 100% domestic supply of albumin preparations produced from donated human blood is difficult and because contamination by materials causing microbial infection of humans cannot be ruled out with such preparations, we began in 1981 to develop rHSA. In October 1997, we filed an application for approval of rHSA preparation with the regulatory authority and obtained approval in October 2007.

(*2) “GMP Inspection concerning Pharmaceuticals” (currently called “GMP Compliance Inspection”)

This is intended to inspect that the manufacturing sites of pharmaceuticals comply the GMP and are manufacturing pharmaceuticals, etc. under appropriate control and management.

GMP (Good Manufacturing Practice) means “standards on manufacturing control and quality control of medicines and quasi-medicines” setting forth the standards and rules to be observed pertaining to manufacturing control of medicines to ensure supply of safe and quality medicines.

(*3) ”Commercial scale validation”

This is intended to verify that a given product manufactured reliably with the manufacturing sites used for commercial production can satisfy the quality standards. To put it concretely, 3 or more lots of the product are usually checked at the relevant manufacturing site before marketing authorization of the product is obtained.

(*4) PCA reaction test in rats

This test is intended to confirm that the product is free of allergenic contaminants (yeast components) by checking for antigen-antibody reactions involving yeast components, because contamination by impurities (yeast components) originating from the cells producing recombinant albumin (yeast) can induce allergy. With this test, a judgment is made on the basis of the size of pigmented spot formed by reaction of the antibody to contaminant yeast components.

PCA stands for “Passive Cutaneous Anaphylaxis” and is intended to check for acute allergic reactions in experimental animals.