

May 20, 2011

Press Release

[Mitsubishi Tanabe Pharma Corporation](#)

**Approval for Additional Indication of Anti-D Human Immunoglobulin
I.M.1000-BENESIS (Dry anti-Rho(D) Immune Human Globulin)**

Osaka, Japan, May 20, 2011---Mitsubishi Tanabe Pharma Corporation (President & CEO: Michihiro Tsuchiya) announced today that its consolidated subsidiary, Benesis Corporation (Head office: Osaka; President: Junichi Watanabe) obtained approval for additional indication of “the sensitization risk due to the D(Rho) factor around the 28th week of pregnancy, or after miscarriage or artificial abortion.” for Anti-D Human Immunoglobulin I.M.1000-BENESIS (dry anti-Rho(D) immune human globulin) as of May 20, 2011.

When a woman with D(Rho) negative blood becomes pregnant and gives birth to a D(Rho) positive child, the red blood cells of the D(Rho) positive baby will enter the maternal circulation of the D(Rho) negative mother through transplacental hemorrhage. As a result, anti-D(Rho) antibodies may be generated in the mother’s body. If this woman becomes pregnant a following time, anti-D(Rho) antibodies will be transmitted via the placenta to the baby in the womb, causing hemolytic disorder in the newborn baby.

This drug inhibits the generation of anti-D(Rho) antibodies in the body of a D(Rho) negative mother who has delivered a D(Rho) positive baby, if administered within 72 hours after delivery. For this indication, the Health, Labor and Welfare Ministry has already given approval, and its efficacy has been widely recognized.

Based on reports, however, that the rate of sensitization to the D(Rho) factor further decreases upon administering this drug around the 28th week of pregnancy, medical guidelines in the United States, Europe and Japan recommend that the drug be administered during the pregnancy itself (around the 28th week of pregnancy). Moreover, medical treatments such as amniocentesis and external versions of the fetal position, miscarriage and ectopic gestation also carry a risk of sensitization due to the D(Rho) factor, medical guidelines in the United States, Europe and Japan recommend that the drug be administered after treatment, operation or miscarriage.

Under these circumstances, the Japan Society of Obstetrics & Gynecology filed a request with the Ministry to review the drug based on the List of Unapproved Drugs/Off-Label Prescription Drugs with High Medical Needs in 2009. In October 2010, the First Committee on Pharmaceutical Products of the Pharmaceutical Affairs and Food Sanitation Council issued a pre-assessment report that an “application for approval of additional indication for a

publicly known prescription” may be filed with the Ministry. Based on this pre-assessment report, Benesis Corporation filed an application for approval of additional indication for a publicly known prescription in November 2010, and the approval was obtained for the sensitization risk due to the D(Rho) factor around the 28th week of pregnancy, or after miscarriage or artificial abortion. .

Mitsubishi Tanabe Pharma and Benesis expect that, by the acquisition of this approval for additional indication, Anti-D Human Immunoglobulin I.M.1000-BENESIS will contribute greatly to the prevention of hemolytic disorders among newborns in pregnancies with rhesus incompatibility.

<Contact for Inquiries>
Corporate Communications Department
Phone: +81 6-6205-5211