July 14, 2026
Pharmaceuticals and Medical Devices Agency, Japan

Summary of Investigation Results

Anti-human thymocyte immunoglobulin, rabbit

<table>
<tr><td rowspan="2">Non-proprietary name
Brand name</td><td>Non-proprietary name</td><td colspan="2">Brand name
(marketing authorization holder)</td></tr>
<tr><td>Anti-human thymocyte immunoglobulin, rabbit</td><td colspan="2">Thymoglobuline I.V. Infusion (Sanofi K.K.)</td></tr>
<tr><td>Japanese market launch</td><td colspan="3">November 2008</td></tr>
<tr><td>Indications</td><td colspan="3">○ Moderate to very severe aplastic anemia
○ Pretreatment prior to hematopoietic stem cell transplantation
○ Acute graft-versus-host disease after hematopoietic stem cell transplantation
○ Treatment of acute rejection after the following organ transplantations:
Renal, liver, heart, lung, pancreas, or small intestinal transplantation</td></tr>
<tr><td>Summary of revisions</td><td colspan="3">“Thrombotic microangiopathy” should be added to the 11.1 Clinically Significant Adverse Reactions section in the 11. ADVERSE REACTIONS.</td></tr>
<tr><td>Investigation results and background of the revision</td><td colspan="3">Cases involving thrombotic microangiopathy were evaluated. Cases in which a causal relationship between anti-human thymocyte immunoglobulin, rabbit, and thrombotic microangiopathy was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.</td></tr>
<tr><td rowspan="2">Reference: Number of cases involving thrombotic microangiopathy reported in Japan and overseas</td><td colspan="2">Japan*1</td><td>Overseas*2</td></tr>
<tr><td colspan="2">A total of 25 cases have been reported to date (including 0 cases in which a causal relationship between the drug and the event was reasonably possible).
A total of 11 deaths have been reported to date (including 0 cases in which a causal relationship between the drug and the death following the event was reasonably possible).</td><td>A total of 8 cases have been reported to date (including 3 cases in which a causal relationship between the drug and the event was reasonably possible).
No deaths have been reported to date.</td></tr>
</table>

*1: Among cases collected in the PMDA's safety database for drugs, cases which correspond to the PTs "Thrombotic microangiopathy," "Haemolytic uraemic syndrome," "Thrombotic thrombocytopenic purpura," "Microangiopathic haemolytic anaemia," and "Microangiopathy" were retrieved.
*2: Among cases collected in the PMDA's safety database for drugs, cases provided by the marketing authorization holder as suspected cases of thrombotic microangiopathy due to drug administration were retrieved.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).