July 14, 2026
Pharmaceuticals and Medical Devices Agency, Japan

Summary of Investigation Results

Ixazomib citrate

<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>Ixazomib citrate</td><td colspan="2">a. Ninlaro capsules 0.5 mg, b. 2.3 mg, c. 3 mg, d. 4 mg (Takeda Pharmaceutical Company Limited)</td></tr>
<tr><td>Japanese market launch</td><td colspan="3">a. November 2024
b. c. d. May 2017</td></tr>
<tr><td>Indications</td><td colspan="3">a.
〇Maintenance therapy of multiple myeloma
b. c. d.
〇Relapsed or refractory multiple myeloma
〇Maintenance therapy of multiple myeloma</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 ixazomib citrate 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>Japan</td><td colspan="2">Overseas</td></tr>
<tr><td>A total of 3 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 1 death has 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 colspan="2">A total of 17 cases have been reported to date (including 4 cases in which a causal relationship between the drug and the event was reasonably possible).
A total of 4 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></tr>
</table>

*: Cases collected in PMDA's safety database for drugs.

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).