July 14, 2026
Pharmaceuticals and Medical Devices Agency, Japan

Summary of Investigation Results

Recombinant RS virus vaccine

<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>Recombinant RS virus vaccine</td><td colspan="2">a. Abrysvo intramuscular injection (Pfizer Japan Inc.)
b. Arexvy Intramuscular Injection (GlaxoSmithKline K.K.)</td></tr>
<tr><td>Japanese market launch</td><td colspan="3">a. May 2024
b. January 2024</td></tr>
<tr><td>Indications</td><td colspan="3">a. Active immunization of pregnant individuals for the prevention of lower respiratory tract disease caused by respiratory syncytial virus in neonates and infants.
Prevention of disease caused by respiratory syncytial virus infection in individuals 60 years of age and older
b. Prevention of disease caused by respiratory syncytial virus infection</td></tr>
<tr><td>Summary of revisions</td><td colspan="3">"Guillain-Barre syndrome" has been added to the section "11.1 Clinically Significant Adverse Reactions" in "11. ADVERSE REACTIONS."</td></tr>
<tr><td>Investigation results and background of the revision</td><td colspan="3">Cases involving Guillain-Barre syndrome were evaluated. Cases in which a causal relationship between these vaccines and Guillain-Barre syndrome was reasonably possible have been reported, and the post-marketing observational study and multiple epidemiological studies on these vaccines have suggested an increased risk of causing Guillain-Barre syndrome. 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 “Guillain-Barre syndrome” reported in Japan and overseas</td><td colspan="2">Japan</td><td>Overseas[*2]</td></tr>
<tr><td colspan="2">a. A total of 0 cases have been reported to date.
b. A total of 0 cases have been reported to date.</td><td>a. A total of 15 cases have been reported to date (including 1 case 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></tr>
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		b. A total of 3 cases have been reported to date. (including 1 case in which a causal relationship between the drug and the event was reasonably possible). No deaths have been reported to date.

*: Cases collected in PMDA's safety database for drugs.
*2: Cases reported under the PT "Guillain-Barre syndrome" that are assessed by the company as Brighton Criteria 1 to 3.

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).