August 25, 2026
Pharmaceuticals and Medical Devices Agency, Japan

Summary of Investigation Results

Talaporfin sodium

Non-proprietary name Brand name	Non-proprietary name	Brand name (marketing authorization holder)
	Talaporfin sodium	Laserphyrin for Injection 100 mg (Meiji Seika Pharma Co., Ltd.)
Japanese market launch	June 2004	
Indications	○ Early-stage lung cancer (Stage 0 or I) treatable with laser irradiation in patients ineligible for other radical interventions including surgical resection, or in patients who require the preservation of pulmonary function but cannot receive other treatments. The entire tumor must be observable endoscopically. ○ Primary malignant brain tumor (only in patients who undergo resection of brain tumor) ○ Local residual/recurrent oesophageal carcinoma after chemoradiotherapy or radiotherapy	
Summary of revisions	1. A cautionary statement regarding oesophageal perforation should be added to the 8. IMPORTANT PRECAUTIONS section. 2. "Oesophageal perforation" and "Oesophageal stenosis" should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.	
Investigation results and background of the revision	Cases involving oesophageal stenosis and oesophageal perforation were evaluated. Cases in which a causal relationship between talaporfin sodium and severe oesophageal stenosis and oesophageal perforation 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.	
Reference: Number of cases*1 involving oesophageal stenosis *2 and oesophageal perforation reported in Japan	< Oesophageal stenosis > A total of 6 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 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). < Oesophageal perforation >	

	A total of 13 cases have been reported to date (including 5 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).

*1: Cases collected in PMDA's safety database for drugs.
*2: Cases that fell under MedDRA ver. 28.1 PT "Oesophageal stenosis" involving serious events of grade 3 or higher according to CTCAE ver. 6.0 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).