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# Summary of Investigation Results

## Axitinib

February 10, 2026

### Non-proprietary name

Axitinib

### Brand name (marketing authorization holder)

Inlyta Tablets 1 mg, 5 mg (Pfizer Japan Inc.)

### Japanese market launch

August 2012

### Indications

Radically unresectable or metastatic renal cell carcinoma

### Summary of revisions

“Acute pancreatitis” 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 acute pancreatitis were evaluated. Cases in which a causal relationship between axitinib and acute pancreatitis 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\* and patient mortalities involving Acute pancreatitis reported in Japan and overseas

A total of 4 cases have been reported in Japan to date (including 1 case in which a causal



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relationship between the drug and the event was reasonably possible).

No patient mortalities have been reported in Japan to date.

A total of 17 cases have been reported overseas to date. (A causal relationship between the drug and the event was reasonably possible for 3 cases, including 1 case in which the drug was administered outside the approved indications).

No patient mortalities have been reported overseas to date.

\*: Among the cases collected in the PMDA's safety database for drugs, those for which information on imaging of the pancreas or test values for pancreatic enzymes (amylase or lipase) is available 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).

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