



Summary of Investigation Results

Axitinib

January 10, 2019

Non-proprietary name

Axitinib

Branded name (Marketing authorization holder)

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

Indications

Unresectable or metastatic renal cell carcinoma

Summary of revisions

“Interstitial lung disease” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of interstitial lung disease have been reported in patients treated with axitinib in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 20 cases involving interstitial lung disease have been reported to date (including 2 cases for which a causal relationship with the product could not be ruled out.)

One instance of patient mortality has been reported to date (a causal relationship with the product could not be established in this case.)