This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Cetuximab sarotalocan sodium（genetical recombination）

June 14, 2022

Non-proprietary name

Cetuximab sarotalocan sodium（genetical recombination）

Brand name (Marketing authorization holder)

Akalux IV Infusion 250 mg (Rakuten Medical K.K.)

Indications

Unresectable, locally advanced or recurrent head and neck cancer

Summary of revisions

1. A statement should be added to the IMPORTANT PRECAUTIONS section that whether a tumour invasion into the skin or mucous membrane has occurred should be adequately confirmed prior to the administration of this drug. In addition, during the treatment with this drug, the patient's condition including the presence or absence of fistula, ulceration or necrosis should be adequately monitored.
2. "Patients with tumour invasion into the skin or mucous membrane" should be added to the PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS section.
3. "Fistula, mucocutaneous ulceration or necrosis" should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of fistula, skin ulceration or necrosis identified in Japan and overseas after treatment with this drug and BioBlade Laser System (hereinafter referred to as "this treatment") were

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

evaluated. Cases for which a causal relationship between this treatment and fistula, etc. was reasonably possible have been reported in Japan and overseas. As a result of consultation with expert advisors, MHLW/PMDA concluded that revision of Precautions was necessary. In addition, as a result of consultation with expert advisors, MHLW/PMDA concluded that a cautionary statement regarding mucosal ulceration and mucosal necrosis was also necessary, taking into account the reports that ulceration or necrosis has occurred in mucous membrane as well.

Number of cases and patient mortalities of fistula, mucocutaneous ulceration or necrosis reported in Japan and overseas during the previous 3 fiscal years

A total of 4 cases have been reported in Japan to date. (A causal relationship between the drug and events was reasonably possible for all the cases.)
No patient mortalities have been reported to date.
(Japanese market launch: January 2021)
1 case has been reported overseas to date. (A causal relationship between the drug and events was reasonably possible for this case.)
No patient mortalities have been reported to date.

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).