*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

# Panitumumab and cetuximab

April 1, 2015

## Non-proprietary name

a. Panitumumab (genetical recombination)

b. Cetuximab (genetical recombination)

## Brand name (Marketing authorization holder)

a. Vectibix Intravenous Infusions 100 mg and 400 mg (Takeda Pharmaceutical Co., Ltd.)

b. Erbitux Injection 100 mg (Merck Serono Co., Ltd.)

## Indications

a. KRAS wild-type, incurable, unresectable, advanced/recurrent colorectal cancer

b. EGFR-positive, incurable, unresectable, advanced/recurrent colorectal cancer
Head and neck cancer

## Summary of revision

The following information should be included in the Precautions for Indications section:

Prior to initiation of treatment, assess the RAS (KRAS and NRAS) gene mutation status and select the suitable patients.

## Background of the revision and investigation results

The efficacy of treatment in patients with or without the RAS (KRAS and NRAS) gene mutation was retrospectively analyzed in a total of 4 phase III studies of panitumumab (genetical recombination) and cetuximab (genetical recombination) involving patients with colorectal cancer. The results revealed a trend that suggested no add-on effect could be expected with co-administration of panitumumab (genetical recombination) or cetuximab (genetical recombination) as

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compared with the control group among the patient population with the RAS gene mutation. Following an investigation based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

**The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan**

N/A