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

Atezolizumab

(genetical recombination)

December 3, 2019

Non-proprietary name

Atezolizumab（genetical recombination）

Branded name (Marketing authorization holder)

a. Tecentriq for Intravenous Infusion 840 mg (Chugai Pharmaceutical Co., Ltd.)

b. Tecentriq for Intravenous Infusion 1200 mg (Chugai Pharmaceutical Co., Ltd.)

Indications

a. PD-L1-positive, hormone receptor-negative and HER2-negative inoperable or metastatic breast cancer

b. Unresectable, advanced or recurrent non-small cell lung cancer, extensive-stage small cell lung cancer

Summary of revisions

“Haemophagocytic syndrome” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of haemophagocytic syndrome have been reported in patients treated with atezolizumab 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.

Pharmaceuticals and Medical Devices Agency

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

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

A total of 8 cases involving haemophagocytic syndrome have been reported to date (including 6 cases for which a causal relationship between the drug and event could not be ruled out). One instance of patient mortality has been reported to date (a causal relationship between the drug and the death subsequent to event could not be ruled out for this case).

(Japanese market launch: April 2018)