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

Mecasermin

(genetical recombination)

December 3, 2019

Non-proprietary name

Mecasermin (genetical recombination)

Branded name (Marketing authorization holder)

Somazon 10 mg for Injection (OrphanPacific, Inc.)

Indications

Improvement of hyperglycemia, hyperinsulinaemia, acanthosis nigricans, and hairiness in the following diseases:

Type A insulin-receptor abnormality, type B insulin-receptor abnormality, lipoatrophic diabetes, leprechaunism, Rabson-Mendenhall syndrome

Improvement of growth disorder in the following diseases:

Growth hormone-resistant isolated growth hormone deficiency type 1A, Laron syndrome

Summary of revisions

Language concerning the post-marketing occurrence of benign or malignant tumors reported in patients treated with mecasermin although causality is unclear should be added to the Precautions concerning Indications section and the statement in the Clinically Significant Adverse Reactions section that the benefits and risks should be considered when using this drug should be transferred to the Precautions concerning Indications section. *

Pharmaceuticals and Medical Devices Agency

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

Investigation results and background of the revision

Several published articles have been reported suggesting an association between human insulin-like growth factor-I which is an ingredient of this drug and occurrence of a tumor. In addition, cases of benign or malignant tumors in patients treated with mecasermin have been reported in Japan and overseas although causality is unclear. 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 cases and patient mortalities reported in Japan during the previous 3 fiscal years

No cases involving benign or malignant tumor have been reported to date.

* Revision reflecting the new instructions for package insert language specified in the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017