



# Summary of Investigation Results

## Preparations containing ipragliflozin L-proline

January 21, 2020

### Non-proprietary name

- a. Ipragliflozin L-proline
- b. Sitagliptin phosphate hydrate/ipragliflozin L-proline

### Branded name (Marketing authorization holder)

- a. Suglat Tablets 25 mg, 50 mg (Astellas Pharma Inc.)
- b. Sujanu Combination Tablets (MSD K.K.)

### Indications

- a. Type 2 diabetes mellitus, Type 1 diabetes mellitus
- b. Type 2 diabetes mellitus, but only if treatment with co-administration of sitagliptin phosphate hydrate and ipragliflozin L-proline is considered appropriate.

### Summary of revisions

- a. "Shock, anaphylaxis" should be added to the Clinically Significant Adverse Reactions section.
- b. "Anaphylactic reaction" in the Clinically Significant Adverse Reactions section should be revised to "shock, anaphylaxis".



## **Investigation results and background of the revision**

Cases of shock or anaphylaxis have been reported in patients treated with Ipragliflozin L-proline 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 cases and patient mortalities reported in Japan during the previous 3 fiscal years**

Cases involving shock or anaphylaxis

- a. A total of 2 cases involving shock or anaphylaxis have been reported to date (A causal relationship between the drug and event could not be established either of these cases.) No patient mortalities have been reported to date.
- b. No cases have been reported to date.  
(Japanese market launch: May 2018)