*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

## Asunaprevir, daclatasvir hydrochloride, daclatasvir hydrochloride/asunaprevir/beclabuvir hydrochloride

January 10, 2019

### Non-proprietary name

a. Asunaprevir
b. Daclatasvir hydrochloride
c. Daclatasvir hydrochloride/asunaprevir/beclabuvir hydrochloride

### Branded name (Marketing authorization holder)

a. Sunvepra Capsules 100 mg (Bristol-Myers Squibb Company)
b. Daklinza Tablets 60 mg (Bristol-Myers Squibb Company)
c. Ximency Combination Tablets (Bristol-Myers Squibb Company)

### Indications

Improvement of viremia in patients with chronic hepatitis C serogroup 1 (genotype 1) or with compensated cirrhosis type C serogroup 1 (genotype 1)

### Summary of revisions

1. A cautionary statement concerning “renal impairment” should be added to the Important Precautions section.
2. “Renal impairment” should be added to the Clinically Significant Adverse Reactions section.



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## Investigation results and background of the revision

Cases of renal impairment have been reported in patients co-administrated daclatasvir hydrochloride and asunaprevir 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 adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

a., b. Co-administration of daclatasvir hydrochloride and asunaprevir

A total of 18 cases involving renal impairment have been reported to date (including 5 cases* for which a causal relationship with the product could not be ruled out.)

No patient mortalities have been reported to date.

c. Daclatasvir hydrochloride/asunaprevir/beclabuvir hydrochloride

No cases involving a renal impairment have been reported to date.

*the possibility of a causal relationship between adverse events observed and the co-administration of daclatasvir hydrochloride and asunaprevir was evaluated.



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