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

Rotigotine

February 25, 2020

Non-proprietary name

Rotigotine

Branded name (Marketing authorization holder)

Neupro patch 2.25 mg, 4.5 mg, 9 mg, 13.5 mg, 18 mg

(Otsuka Pharmaceutical Co., Ltd.)

Indications

Neupro patch 2.25 mg, 4.5 mg:

- Parkinson's disease
- Moderate to severe idiopathic restless legs syndrome

Neupro patch 9 mg, 13.5 mg, 18 mg:

- Parkinson's disease

Summary of revisions

"Rhabdomyolysis" should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of rhabdomyolysis have been reported in patients treated with rotigotine in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

Pharmaceuticals and Medical Devices Agency

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

Cases involving rhabdomyolysis

A total of 4 cases have been reported to date (including 3 cases for which a causal relationship between the drug and event could not be ruled out). No patient mortalities have been reported to date.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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