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News Release

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Execution of a Plea Agreement with the U.S. Department of Justice

As announced in the Financial Results (Tanshin) for the fiscal years ended March 31, 2015 and March 31, 2016 and the news release titled as “Notice Concerning the Revision to Financial Forecast” dated November 6, 2018, in March and August 2015, subpoenas were issued to Olympus Medical Systems Corp. (OMSC), a subsidiary of ours, by the U.S. Department of Justice (DOJ), seeking information relating to duodenoscopes that the Olympus Group manufactures and sells, and the Department had continued an investigation relating to the U.S. Federal Food, Drug and Cosmetic Act (FDCA).

On December 3, 2018, OMSC entered into a plea agreement, described further below, with the DOJ regarding this matter. The agreement was approved by a U.S. federal court and thus became final on December 10, 2018 (U.S. Eastern Time), and so we hereby inform you as follows.

1. Outline

Subpoenas were issued to OMSC by DOJ in March and August 2015, seeking information relating to duodenoscopes that were sold in the United States, and the DOJ has since continued an investigation relating to the FDCA. A plea agreement covering the terms of the settlement was announced by the DOJ at a public sentencing hearing on December 10, 2018.

2. Agreements

With respect to this matter, OMSC has entered into a plea agreement with the DOJ on issues related to filing and supplementing Medical Device Reports (MDRs) to the U.S. Food and Drug Administration (FDA) regarding adverse events associated with the TJF-Q180V and agreed, among other things, that:

- (i) it will enter a guilty plea to three criminal misdemeanors in the U.S. District Court for the District of New Jersey for failure to submit, to the FDA, two required supplemental MDRs and one initial MDR for events in Europe between August 2012 and October 2014.
- (ii) it will pay a criminal fine in the amount of U.S. \$80 million (approximately [] yen) and criminal forfeiture in the amount of U.S. \$5 million (approximately [] yen); and
- (iii) it will undertake steps to enhance its regulatory compliance processes and procedures, and to regularly make certain certifications that the Company is meeting the expectations of the settlement.

3. Financial Impact and Future Outlook

With respect to this matter, we recorded a reserve in the amount of 9,653 million yen in the financial results for the cumulative second quarter of the fiscal year ending March 31, 2019.

Further, no revision is made to the consolidated financial forecast for the fiscal year ending March 31, 2019 due to this matter.

The settlement does not impact the availability of Olympus products and services worldwide.