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# Anti-Influenza Drug, “Tamiflu® Dry Syrup 3%,” Obtained Approval for Additional Dosage and Administration for Newborns and Infants

TOKYO, March 24, 2017 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it obtained an approval for anti-influenza drug “Tamiflu® Dry Syrup 3%” (oseltamivir phosphate) for the dosage and administration of treatment of influenza type A or B virus infection to newborns and infants from the Japanese Ministry of Health, Labour and Welfare.

As a result of the evaluation by the “Review Committee on Unapproved Drugs and Indications with High Medical Needs”* held on November 16, 2016, Tamiflu was recognized to be entitled to file a public knowledge-based application for the indication of treatment of influenza type A or B virus infection to newborns and infants. With this evaluation, Tamiflu was formally allowed to use of a public knowledge-based application at the “Second Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council” held on November 24. The additional dosage and administration was requested by The Japanese Association for Infectious Disease, Japanese Society for Pediatric Infectious Diseases, and Japan Society for Premature and Newborn (the present, Japan Society for Neonatal Health and Development).

Through the provision of the new treatment options, Chugai will continue its effort to contribute to influenza infection treatment and to make efforts for promoting the proper use.

* The “Review Committee on Unapproved Drugs and Indications with High Medical Needs” was established for the purpose of enhancing development by the pharmaceutical companies of drugs and indications that have been approved for use in western countries but not yet approved in Japan, through activities such as evaluating medical needs and confirming the applicability of “public knowledge-based application” and investigating the need for studies that should be additionally conducted.”



[Drug Information] Indication with underlined is newly added.

Brand name: Tamiflu® Dry Syrup 3%

Generic name: Oseltamivir phosphate

Indications: Treatment and prevention of influenza type A or B virus infection

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Dosage and administration:

1. When used for treatment

1) Adults

Usually, 75 mg as oseltamivir is suspended before use and administered orally twice a day for 5 days.

2) Children

Usually, the dosage below is suspended before use and administered orally twice a day for 5 days. However, the maximum dose per administration is 75 mg as oseltamivir.

Children and young children: 2 mg/kg as oseltamivir (66.7 mg/kg as Dry Syrup)

Neonates and infants: 3 mg/kg as oseltamivir (100 mg/kg as Dry Syrup)

Drug price: JPY 244.00/gram

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