

December 22, 2011

ONO PHARMACEUTICAL CO., LTD.

President and Representative Director: Gyo Sagara

Code No.: 4528 at the 1st section of Tokyo/Osaka Stock Exchange

INQUIRIES: Kinya Morimoto, Executive Officer, Director, Corporate Communications

Leukotriene Receptor Antagonist “Onon[®] Dry Syrup 10%” has received approval for the additional indication of allergic rhinitis

Ono Pharmaceutical Co., Ltd. (Osaka, Japan) today announced that leukotriene receptor antagonist “Onon[®] Dry Syrup 10%” (Onon[®] Dry Syrup) has received approval for the additional indication of allergic rhinitis on 22 December 2011.

“Onon[®] Dry Syrup” was launched in January 2000 as a pediatric preparation of “Onon[®] Capsule 112.5mg”, an agent for bronchial asthma and allergic rhinitis, and has been widely used for pediatric patients with bronchial asthma. “Onon[®] Dry Syrup”, however, had not been approved for the treatment of allergic rhinitis, and there was a strong demand for the drug to obtain an additional indication of allergic rhinitis in clinical practice. “Japanese Society of Allergology” and “Japanese Society of Pediatric Allergy and Clinical Immunology” therefore submitted a request to Ministry of Health, Labor and Welfare for the indication.

In response to the demand in clinical practice, Ono had developed Onon[®] Dry Syrup for the treatment of allergic rhinitis and filed an application for the additional indication in April this year.

The company is very much delighted that the allergic rhinitis indication was finally approved and expect that the drug will be widely used for pediatric patients with allergic rhinitis as well as bronchial asthma. The company will continue its utmost effort to meet unmet medical needs.

*Please refer to the product summary of Onon[®] Dry Syrup in the following page.

PRODUCT SUMMARY.

(Newly approved Indication is shown in bold type and underlined)

Trade Name Onon[®] Dry Syrup 10%

Generic Name (INN) Pranlukast Hydrate

Indications Bronchial asthma
Allergic rhinitis

Dosage and Administration For pediatric use, daily dosage of pranlukast hydrate is 7mg/kg (70 mg/kg as dry syrup) that is divided into two dosing, one after breakfast and another after dinner, and orally administered in suspended form. Dosage is decreased or increased according to age and symptoms. The maximum daily dosage of pranlukast hydrate is 10mg/kg (100mg/kg as dry syrup). However, it should not exceed 450 mg/day (4.5g/day as dry syrup), which is daily dosage for adults.
For standard one time dosage by weight was shown in the below table, which is administered twice daily after breakfast and dinner.

Weight	One time dosage of dry syrup
More than 12 kg and less than but not including 18 kg	0.5g (50mg as pranlukast hydrate)
More than 18 kg and less than but not including 25 kg	0.7g (70mg as pranlukast hydrate)
More than 25 kg and less than but not including 35 kg	1.0g (100mg as pranlukast hydrate)
More than 35 kg and less than but not including 45 kg	1.4g (140mg as pranlukast hydrate)