September 20, 2005

Public Relations
Ono Pharmaceutical Co., Ltd.
Tel: +81-6-6263-5670
Fax: +81-6-6263-2950

Changes to the Development Program for ONO-4128 / 873140

Ono Pharmaceutical Co., Ltd. ("Ono") announced today that GlaxoSmithKline ("GSK") has made changes to the development program for its investigational CCR5 entry inhibitor (ONO-4128 / 873140) due to potential safety issues observed in Phase IIb studies performed by GSK in North America and Europe. GSK has received reports of elevated liver function test values (AST, ALT and total bilirubin) in these clinical trials. ONO-4128 / 873140 was discovered by Ono and licensed to and developed by GSK on a worldwide basis.

After review of these liver toxicity findings with the US Food and Drug Administration, GSK immediately terminated these Phase IIb studies with ONO-4128 / 873140 in treatment-naïve patients. In addition, GSK will continue its ongoing Phase III studies involving treatment-experienced patients ,but make changes to its protocol including patient inclusion/exclusion criteria.

Accrording to GSK, treatment-experienced patients already enrolled in the Phase III studies may continue on their study medication but will be monitored closely for signs or symptoms of hepatotoxicity and/or elevations in liver function tests.

(Reference)

- ONO-4128 / 873140

  The human CCR5 receptor is believed to be the predominant co-receptor used by HIV. ONO-4128 / 873140 appears to block the entry of HIV into human cells through a new mechanism of action that is totally different from those of currently available antiretroviral drugs.

- The License Agreement for ONO-4128 / 873140 between Ono and GSK

  Ono entered a worldwide license agreement with GSK on the development, manufacturing and commercialization of ONO-4128 / 873140 in December 2002. Under the terms of the agreement, GSK will have exclusive worldwide development, manufacturing and commercialization rights for ONO-4128. Ono will receive an up-front payment, clinical and regulatory milestone payments and royalties based on total worldwide annual net sales.