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Phase I Clinical Study with New HIV Drug (Oral CCR5 Antagonist) Completed in the US

Ono Pharmaceutical Co., Ltd. (Ono) announced that GlaxoSmithKline (GSK) has completed the first single and repeat dose Phase I clinical study in the US with a new HIV drug from Ono (development code: GW873140 [ONO-4128]). GW873140 (ONO-4128) was licensed to GSK by Ono in December 2002 for worldwide development, manufacture and sales.

The human CCR5 receptor is believed to be the predominant co-receptor used by HIV in the early and middle stages of infection. GW873140 (ONO-4128) appears to block the entry of HIV into human cells through a new mechanism of action that is different from marketed HIV drugs. In addition, since the CCR5 receptor exists on the surface of human immune cells, the possibility of viral resistance being developed by mutant HIV might be lower; however, this theory must be evaluated in human clinical trials.

GW873140 (ONO-4128) appears to be well-tolerated based on preliminary data from a Phase I clinical study initiated in the US in June 2003 in healthy adult subjects. Because GW873140 (ONO-4128) appears to bind to the CCR5 receptor for an extended period of time, an oral formulation with fewer administrations and lower dosage is being considered for the development program.

According to GSK, a Phase II study will be initiated shortly, and NDA filing is expected to be in the first half of 2007.