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Ono and GlaxoSmithKline Signed a Worldwide Agreement on Development and Commercialisation of a New HIV Drug

Ono Pharmaceutical Co., Ltd. (head office: Osaka, Japan) announced today that it signed a worldwide license agreement with GlaxoSmithKline plc (head office: London, England) on the development, manufacturing and commercialisation of Ono's cellular chemokine receptor (CCR5) antagonist, ONO-4128, currently in preclinical development for HIV, as well as for associated back-up and follow-on compounds. The parties also will explore the utility of CCR5 antagonists in non-HIV conditions.

This agreement is based on Ono's strategy for quicker global development and launch of its HIV drug by partnership with a Western big firm having broad experience in this field, and serves also GSK's aim of enhancing its HIV franchise by acquiring a novel anti-HIV compound with a new mechanism of action.

Under the terms of the agreement, GSK will have exclusive worldwide development, manufacturing and commercialisation 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. Ono will also receive separately milestone payments in the event GSK develops ONO-4128 and associated back-up and follow-on compounds in the field other than HIV. Ono retains exclusive rights to develop and commercialise ONO-4128 as well as associated back-up and follow-on compounds in the non-HIV field in Japan, South Korea and Taiwan.

Research to date revealed that human cells acquire AIDS virus after the virus binds to a receptor called CCR5. ONO-4128 is an orally effective low molecular compound created by genomic drug design technology and prevents HIV viral infection by blocking the binding of the virus to the CCR5 receptor. This mechanism of action is different from those of conventional drugs such as reverse transcriptase inhibitors and protease inhibitors which inhibit multiplication of HIV virus. Multi-drug resistance caused by viral mutation is often the problem with existing drugs. However, the likelihood of resistance may be lower for CCR5 antagonists since these receptors reside on the surface of human immune cell (cell membrane).

GSK plans to initiate Phase I clinical studies in the USA in the first half of 2003 if all goes smoothly.