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Sanofi signs exclusive deal for OTC rights to Tamiflu

24 July 2019 | News

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Sanofi signed an agreement with Roche for the exclusive over-the-counter (OTC) rights to Tamiflu® for the prevention and treatment of influenza or flu in the US. Under the terms of the agreement, Sanofi will be responsible for leading FDA negotiations for the OTC switch and subsequent exclusive marketing, scientific engagement and distribution of Tamiflu OTC in the US. Tamiflu is currently sold in the US by Genentech, a member of the Roche Group, for prescription use.

“This is a strategic and important transaction for us as we strive to continually bring innovations to the market,” says Alan Main, Executive Vice President, Consumer Healthcare, Sanofi. “The US market is the largest OTC market in the world and a successful switch of Tamiflu to OTC would support our global cough and cold strategy by expanding into flu with a sustainable point of difference in the market. Tamiflu will offer a significant public health benefit once switched by providing increased access to a safe and efficacious treatment for the prevention and treatment of flu. People would be able to either reduce their chances of getting the flu or, at the first signals, appropriately treat as early as possible during the crucial first 48 hours without having to wait for a doctor’s appointment.”

Flu is a condition for which there is no effective OTC anti-viral treatment. Currently consumers are only able to treat flu symptoms with the available OTC products. Early treatment will help prevent unnecessary spread of the disease. According to the Centers for Disease Control and Prevention (CDC), over 31 million people in the US suffer from the flu in the US each year, but only about 7 million were treated with an effective product like Tamiflu in 2017.

Under the agreement, in addition to leading the FDA negotiations, Sanofi will be responsible for leading the clinical program and funding all studies needed to support the OTC switch in the US in consultation with leading experts in the field. Roche will continue to market Tamiflu in the rest of the world. Sanofi will retain the rights to first negotiations for switch rights in other selected markets.