

Basel, 22. January 2010

Committee for Medicinal Products for Human Use (CHMP) gives positive opinion for Tamiflu Intravenous Compassionate Use Programme in Europe

The Committee for Medicinal Products for Human Use (CHMP) has given a positive opinion for the use of Tamiflu (oseltamivir) intravenous (IV) for compassionate use. Compassionate use programmes are intended to serve as a mechanism for a patient (e.g., severely ill patients) to gain access to a drug on humanitarian grounds before the drug has received official marketing license. This is the first CHMP Opinion for a compassionate use program in Europe.

Intravenous oseltamivir has not received marketing authorization in the EU, or any other jurisdiction, but may be made available for use on compassionate grounds in the following clinical situations:

- IV oseltamivir should be considered only to treat certain hospitalized adult and paediatric patients with acute severe illness due to suspected or confirmed pandemic (H1N1) infection or infection due to seasonal influenza A or B virus.

Specifically, oseltamivir infusion should only be used for the following patients who are admitted to a hospital and under the care or consultation of a licensed clinician (skilled in the diagnosis and management of patients with potentially life-threatening illness and the ability to recognise and manage medication-related adverse events):

- Adult or paediatric patients ≥ 1 year of age with severe influenza illness for whom therapy with an IV agent is clinically indicated, based upon one or more of the following reasons:
 - (1) patient not responding to either oral or inhaled approved antiviral therapy, or

- (2) drug delivery by a route other than IV (e.g. enteral oseltamivir or inhaled zanamivir) is not expected to be dependable or is not feasible, or
- (3) the clinician judges IV therapy is appropriate due to other circumstances.

The clinical studies intended to support the marketing approval of Tamiflu IV are ongoing.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients.

In 2008, Roche had over 80'000 employees worldwide and invested almost 9 billion Swiss francs in R&D. The Group posted sales of 45.6 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

All trademarks used or mentioned in this release are protected by law.