

## Current information

### Today's routine meeting with FDA

- As a regular part of the Best Pharmaceuticals for Children Act, the FDA's Pediatric Advisory Committee reviews post-marketing information on a total of eight medicines, including Tamiflu, today November 18. This routine meeting was scheduled as part of the FDA's overall safety review of drugs that were granted exclusivity based on pediatric studies.

### Worldwide safety data

- Tamiflu has been used in 33 million patients worldwide, including over 13 million children.
- Mortality in patients taking Tamiflu, both in adults and children, is lower than in influenza patients who are not treated with Tamiflu. Based on independent studies, death rates in children treated with Tamiflu are reduced between 60 to 90 percent.
- There is no increase in neuropsychiatric events in patients on Tamiflu versus influenza patients in general. It is important to know that neuropsychiatric events can occur often with influenza patients. Beginning in the mid-1990s, there have been many reports in the pediatric scientific literature describing a syndrome of influenza-associated encephalitis (inflammation of the brain) or encephalopathy.
- Therefore, Roche is confident that Tamiflu can be used safely and effectively by children as well as adults.

### Further information

- In Japan, where 11.6 million children (24.5 million patients in total, adults and children) have taken Tamiflu since 2001, there have been 12 deaths of children from 1 to age 16. In many of these cases, a relationship to Tamiflu was difficult to assess because of the use of other medications and/or presence of other medical conditions. At least 8 of these had significant pre-existing diseases such as kidney impairment, congenital central nervous system disease and asthma, or major complications of influenza, including pneumonia, pulmonary edema, myocarditis, and pancreatitis.
- Facts & Figures on Tamiflu: [www.roche.com/med\\_mbfstamiflu.pdf](http://www.roche.com/med_mbfstamiflu.pdf)
- FDA's Pediatric Advisory Committee: [www.fda.gov/ohrms/dockets/ac/05/slides/2005-4180s1.htm](http://www.fda.gov/ohrms/dockets/ac/05/slides/2005-4180s1.htm)
- FDA's Q&A on Tamiflu: [www.fda.gov/cder/drug/infopage/tamiflu/QA20051117.htm](http://www.fda.gov/cder/drug/infopage/tamiflu/QA20051117.htm)