INFORMATION PAPER

DASG-HCA
17 April 2006

SUBJECT: Influenza and Zanamivir

1. PURPOSE. To provide information about the antiviral medication zanamivir (Relenza®, GlaxoSmithKline) in treating or preventing influenza.

2. FACTS.

a. Influenza is a respiratory illness caused by infection with an influenza virus. Influenza is not the “common cold.” Influenza outbreaks occur each year and result in about 36,000 deaths in the United States and 200,000 excess hospitalizations. The risk of influenza infection and its complications is higher in the elderly, young children and people with chronic diseases.

b. An influenza pandemic is a worldwide outbreak of influenza illness caused by a new or changed influenza virus. All past influenza pandemics resulted from type A influenza viruses. Usually, influenza viruses that infect birds and other animals do not cause serious illness in people. However, influenza viruses can change over time (mutate). If an influenza virus in birds undergoes significant changes, it may be capable of causing serious infection in humans.

c. An avian influenza virus (“bird flu”) is currently circulating in Asia and the Middle East and is responsible for over 194 human infections since 1997. This virus is influenza type A, subtype H5N1. Sustained human-to-human transmission (a requirement for a pandemic) has not yet occurred.

d. Immunization remains the primary strategy to prevent influenza illness. However, in the early months of a pandemic, a vaccine effective against the pandemic-causing influenza virus may not be available. Until a vaccine is available in adequate supply, antiviral medications (the viral version of an antibiotic) known as neuraminidase inhibitors may be of value. Both zanamivir (Relenza®, manufactured by GlaxoSmithKline) and oseltamivir (Tamiflu®, manufactured by Roche Pharmaceuticals) are approved by the Food & Drug Administration (FDA) to prevent and treat influenza disease. Studies show zanamivir and oseltamivir are 70% to 90% effective at preventing influenza. There is little information available on the effectiveness of either zanamivir or oseltamivir in treating or preventing H5N1 disease.

e. Zanamivir is available as a powder for inhalation. The powder is packaged in foil blisters known as a Rotadisk® and inhaled by using a special inhalation device known as a Diskhaler®. Each circular-shaped Rotadisk has four blisters containing 5 mg of zanamivir powder and each product package contains five Rotadisks® and one Diskhaler® equal to one patient treatment. People should be instructed in the use of the delivery system. Instructions should include a demonstration whenever possible. If

zanamivir is prescribed for children, it should be used only under adult supervision and instruction, and the supervising adult should first be instructed by a healthcare professional

f. Treatment: The recommended dose of zanamivir for treatment of influenza in adults and pediatric patients ages 7 years of age and older is 2 inhalations (one 5-mg blister per inhalation for a total dose of 10 mg) twice daily (approximately 12 hours apart) for 5 days. Two doses should be taken on the first day of treatment whenever possible provided there is at least 2 hours between doses. On subsequent days, doses should be about 12 hours apart (e.g., morning and evening) at approximately the same time each day. There are no data on the effectiveness of treatment with zanamivir when initiated more than 2 days after the onset of signs or symptoms.

g. Prophylaxis: Household Setting: The recommended dose of zanamivir for prophylaxis of influenza in adults and pediatric patients 5 years of age and older in a household setting is 10 mg once daily for 10 days. The 10-mg dose is provided by 2 inhalations (one 5-mg blister per inhalation). The dose should be administered at approximately the same time each day. There are no data on the effectiveness of prophylaxis with zanamivir in a household setting when initiated more than 1.5 days after the onset of signs or symptoms in the index case.

h. Community Outbreaks: The recommended dose of zanamivir for prophylaxis of influenza in adults and adolescents in a community setting is 10 mg once daily for 28 days. The 10-mg dose is provided by 2 inhalations (one 5-mg blister per inhalation). The dose should be administered at approximately the same time each day. There are no data on the effectiveness of prophylaxis with zanamivir in a community outbreak when initiated more than 5 days after the outbreak was identified in the community. The safety and effectiveness of prophylaxis with zanamivir have not been evaluated for longer than 28 days duration.

i. The most common side effects reported with zanamivir administration are cough, headache and stomach upset. But these symptoms occur at rates no higher than those reported by people receiving a placebo.

j. Zanamivir should not be used by people with chronic lung problems like asthma. Use of zanamivir may cause airways to constrict or spasm in these people. When zanamivir is used by children, an adult should supervise administration whenever possible.

k. Zanamivir should not be used during pregnancy, because there is insufficient evidence from people to evaluate any risk to either the fetus or pregnant mother. Using zanamivir during pregnancy should be limited to situations where the potential benefit of treating or preventing influenza illness justifies the potential risk to the fetus.

l. Zanamivir is not recommended in women who are nursing, because there is insufficient evidence to evaluate risk to mother or child.

m. Resistance (the ability of the virus to evade the effects of zanamivir) is considered rare. Whether this low rate of resistance will continue with expanded use of zanamivir is unknown.

3. SUMMARY.

a. Immunization remains the primary strategy to prevent serious influenza illness. However, no FDA-licensed vaccine is currently available to prevent influenza A/H5N1 (“bird flu”). New forms of influenza virus may develop too quickly for vaccines to be useful in treating people who are already infected with new viruses.

b. Zanamivir may be useful for people who are not yet immunized or inadequately protected by immunization (e.g., with a vaccine not specific to the circulating virus).

c. Zanamivir is FDA-approved for treatment of influenza in adults and children seven years of age and older who do not have a chronic lung disease and for preventing influenza illness in children and adults five years of age and older.

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