**INFORMATION FOR HEALTHCARE PROVIDERS REGARDING FLUMIST® QUADRIVALENT (INFLUENZA VACCINE LIVE, INTRANASAL) DURING THE 2016-17 INFLUENZA SEASON**

AstraZeneca

AstraZeneca wants to ensure healthcare providers are aware of important information regarding the use and availability of FluMist Quadrivalent during the 2016-17 influenza season. Prior to administering FluMist Quadrivalent, healthcare providers must communicate three pieces of information; awareness of this information is important when considering and discussing influenza vaccination options with patients.

- On June 22, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation that FluMist Quadrivalent should not be used during the 2016-17 influenza season. This ACIP vote was based on data showing that FluMist Quadrivalent demonstrated poor or relatively lower effectiveness during two recent seasons (2013-14 and 2015-16) in which A/H1N1pdm09 influenza strains predominated. More information can be found on the CDC website: http://www.cdc.gov/media/releases/2016/s0622-laiv-flu.html The American Academy of Pediatrics (AAP) supports the ACIP decision.

- The Food and Drug Administration (FDA) has approved FluMist Quadrivalent influenza vaccine for the 2016-17 season. More information can be found on the FDA website: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm293952.htm

- Without an ACIP recommendation for use, healthcare insurers may not provide reimbursement for FluMist Quadrivalent or its administration. This may require some patients to pay the full cost for this vaccine product or a higher cost share than they have paid in prior seasons.

FluMist Quadrivalent is for prevention of seasonal flu in eligible people ages 2 to 49. Contraindications include severe allergic reactions to FluMist or egg protein, and concomitant aspirin therapy in children and adolescents.

Additional Important Safety Information is included in this communication.

**Healthcare providers who decide to purchase product should contact (Distributor's Name/Contact Information) FluMist Quadrivalent distributor directly.**

**Important Safety Information**

FluMist® Quadrivalent (Influenza Vaccine Live, Intranasal) is a vaccine indicated for active immunization of persons 2-49 years of age for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. FluMist Quadrivalent is for intranasal administration only.

FluMist Quadrivalent is contraindicated in persons who have had a severe allergic reaction (e.g., anaphylaxis) to any vaccine component, including egg protein, or after a previous dose of any influenza vaccine, and in children and adolescents receiving concomitant aspirin or aspirin-containing therapy.

In clinical trials, the risks of hospitalization and wheezing were increased in children <24 months of age who received trivalent FluMist® (Influenza Vaccine Live, Intranasal). Children <5 years of age with recurrent wheezing and persons of any age with asthma may be at increased risk of wheezing following FluMist Quadrivalent administration. FluMist Quadrivalent has not been studied in persons with severe asthma or active wheezing. If Guillain-Barré syndrome has occurred within 6 weeks of any prior influenza vaccination, the decision to give FluMist Quadrivalent should be based on careful consideration of the potential benefits and risks. FluMist Quadrivalent has not been studied in immunocompromised persons. The safety of FluMist Quadrivalent in individuals with underlying medical conditions predisposing them to wild-type influenza infection complications has not been established. FluMist Quadrivalent may not protect all individuals receiving the vaccine.

The most common solicited adverse reactions (occurring ≥10% in vaccine recipients and at least 5% greater than in placebo) reported after FluMist were runny nose or nasal congestion in all persons 2-49 years, fever >100°F in children 2-6 years, and sore throat in adults 18-49 years. Among children 2-17 years who received FluMist Quadrivalent, 32% reported runny nose or nasal congestion and 7% reported fever >100°F. Among adults 18-49 years who received FluMist Quadrivalent, 44% reported runny nose or nasal congestion and 19% reported sore throat.

**Please see accompanying full Prescribing Information for FluMist Quadrivalent, including Patient Information.**

If you have any questions regarding FluMist Quadrivalent, please feel free to contact AstraZeneca Medical Information at 1-877-633-4411.