Flublok® Quadrivalent (influenza vaccine) – New Formulation Approval

- On October 7, 2016, the FDA approved Protein Sciences Corporation's Flublok Quadrivalent (influenza vaccine), for active immunization against disease caused by influenza A subtype viruses and type B viruses contained in the vaccine for use in persons 18 years of age and older.

- Flublok Quadrivalent protects against 4 strains of influenza, 3 of the same strains found in trivalent Flublok® plus an additional B strain. Flublok Quadrivalent contains three times more active ingredient than all other quadrivalent vaccines (eg, Afluria® Quadrivalent, Fluarix® Quadrivalent, Flucelvax® Quadrivalent, Flulaval® Quadrivalent, and Fluzone® Quadrivalent).

    — Refer to the individual drug labels for the FDA-approved age ranges.

- The relative efficacy of Flublok Quadrivalent was demonstrated in a clinical study of 8,963 adults (≥ 50 years old). Subjects who received Flublok Quadrivalent were over 40% less likely to get cell-culture confirmed influenza than those that received a leading egg-produced quadrivalent flu vaccine.

    — In addition, the efficacy of Flublok is relevant to Flublok Quadrivalent because both vaccines are manufactured using the same process and have overlapping compositions. The efficacy of Flublok (trivalent formulation) in protecting against influenza illness was evaluated in a placebo-controlled, multicenter trial conducted in the U.S. during the 2007 – 2008 influenza season in adults 18-49 years of age.

- Warnings and precautions with Flublok Quadrivalent include managing allergic reactions, Guillain Barré Syndrome, altered immunocompetence, and limitations of vaccine effectiveness.

- In adults 18 through 49 years of age, the most common adverse reactions (≥ 10%) with Flublok Quadrivalent use were tenderness and pain at the injection site, headache, fatigue, myalgia, and arthralgia.

- In adults 50 years of age and older, the most common adverse reactions (≥ 10%) with Flubok Quadrivalent use were tenderness and pain at the injection site, headache, and fatigue.

- Flublok is administered as a single intramuscular 0.5 mL dose.

- Protein Sciences Corporation plans to launch Flublok Quadrivalent as 0.5 mL single dose pre-filled syringes in 2017.