ASTRAZENECA PLC
Form 6-K
December 06, 2013

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For the month of December 2013

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F X Form 40-F __

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes __ No X

If “Yes” is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-_____

EUROPEAN COMMISSION APPROVES FLUENZ TETRA

FOR THE PREVENTION OF SEASONAL INFLUENZA IN CHILDREN

First and only intranasal four-strain influenza vaccine available in Europe

AstraZeneca today announced that the European Commission (EC) has granted Marketing Authorisation to FluenzTM Tetra. Fluenz Tetra is a nasally administered four-strain live attenuated influenza vaccine for the prevention of influenza in children and adolescents from 24 months up to 18 years of age. The EC approval makes Fluenz Tetra the first and only intra-nasal four-strain influenza vaccine available in Europe.

Historically, seasonal flu vaccines have contained three strains of influenza: two influenza A viruses (H1N1 and H3N2) and one influenza B virus. Fluenz Tetra contains an additional influenza B strain. Over the past decade, influenza B strains accounted for approximately 25 percent of the influenza strains circulating in Europe.

"Fluenz Tetra represents the next generation of influenza vaccine and we are pleased that it is now approved in Europe," said Filip Dubovsky, Vice President of Clinical Biologics Infectious Disease and Vaccines at MedImmune, AstraZeneca's global biologics research and development arm. "The inclusion of a second influenza B strain will broaden the coverage of Fluenz Tetra and should have a valuable public health impact."

The Marketing Authorisation of Fluenz Tetra is based on data from a pivotal paediatric study.
Findings showed that Fluenz Tetra demonstrated a safety and immunogenicity profile that was comparable to Fluenz™, a three-strain (trivalent) live attenuated influenza vaccine already approved in Europe.

The EC decision follows a positive opinion from the Committee for Medicinal Products for Human Use on 19 September 2013, and is applicable to all 28 member states and the three European Economic Area countries of the European Union.

NOTES TO EDITORS

About Influenza
Influenza is the most common vaccine-preventable disease in the developed world. In Europe and throughout the world, influenza creates a significant medical and economic burden. According to World Health Organization (WHO) estimates, seasonal influenza results in three to five million cases of severe illness and up to half a million deaths globally each year. Rates of infection are highest among children, and school-aged children are recognised as the main transmitters of the flu virus. Vaccinating children can lower the overall burden of influenza. This is achieved through direct protection of the child and through indirect effects that are a result of decreased transmission of the virus from children to others in the community, often referred to as herd immunity.

About Fluenz Tetra
Fluenz Tetra is formulated to contain four live attenuated influenza virus strains that are weakened so as to not cause illness.The vaccine is administered by spraying into each nostril where it induces protective immunity. The most common adverse reactions for Fluenz Tetra include runny nose or nasal congestion.

Fluenz Tetra will replace the Fluenz™ three-strain (trivalent) live attenuated influenza vaccine from the 2014-2015 flu season onwards.

In the US, Fluenz Tetra is marketed by MedImmune Specialty Care Division of AstraZeneca, under the trade name FluMist® Quadrivalent (Influenza Vaccine Live, Intranasal). FluMist Quadrivalent was approved by the US Food and Drug Administration (FDA) on 29 February 2012.

About Tetravalent Influenza Vaccines
Vaccine strains are recommended annually by the World Health Organization (WHO) based on anticipated circulating influenza strains for the upcoming season. Historically, seasonal flu vaccines have been trivalent formulations, meaning they contain three strains of influenza: one influenza A (H1N1) virus, one influenza A (H3N2) virus, and one influenza B virus. However, new tetravalent (also referred to as quadrivalent) flu vaccines contain two strains of influenza A and two strains of influenza B to provide broad protection against influenza B.

Since 2001, influenza B strains from two different lineages (B/Yamagata and B/Victoria) have co-circulated each influenza season in Europe. Trivalent vaccine formulations rely on predictions of which influenza B strains will be dominant in the upcoming season. However, B strain circulation has been difficult to predict correctly, and in the last decade, the vaccine B strain only matched the dominant circulating B strain about every other year.

About MedImmune

MedImmune is the worldwide biologics research and development arm of AstraZeneca. MedImmune is pioneering innovative research and exploring novel pathways across key therapeutic areas, including respiratory, inflammation and autoimmunity; cardiovascular and metabolic disease; oncology; neuroscience; and infection and vaccines. The MedImmune headquarters is located in Gaithersburg, Md., one of AstraZeneca's three global R&D centers. For more information please visit www.medimmune.com

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit www.astrazeneca.com

CONTACTS

Media Enquiries
Esra Erkal-Paler +44 20 7604 8030 (UK/Global)
Vanessa Rhodes +44 20 7604 8037 (UK/Global)
Ayesha Bharmal +44 20 7604 8034 (UK/Global)
Tracy Rossin +1 301 398 1468 (US)
Jacob Lund +46 8 553 260 20 (Sweden)

Investor Enquiries
Karl Hård +44 20 7604 8123 mob: +44 7789 654364
Colleen Proctor + 1 302 886 1842 mob: +1 302 357 4882
Anthony Brown +44 20 7604 8067 mob: +44 7585 404943
Jens Lindberg +44 20 7604 8414 mob: +44 7557 319729

06 December 2013

- ENDS -

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 06 December 2013

By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary