ASTRAZENECA PLC
Form 6-K
February 05, 2019

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 February 2019

Commission File Number: 001-11960

AstraZeneca PLC

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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-_____

AstraZeneca PLC

INDEX TO EXHIBITS

1.
EMA grants PRIME eligibility for MEDI8897

5 February 2019 07:00 GMT

EMA grants PRIME eligibility for potential
next-generation RSV medicine MEDI8897

First EMA PRIME eligibility for AstraZeneca

Eligibility based on positive primary analysis of the
Phase IIb trial to evaluate the safety and efficacy of MEDI8897

AstraZeneca and its global biologics research and development arm, MedImmune, today announced that the European Medicines Agency (EMA) has granted access to its PRIME (PRIority MEdicines) scheme for MEDI8897, an extended half-life respiratory syncytial virus (RSV) F monoclonal antibody (mAb) being developed for the prevention of lower respiratory tract infection (LRTI) caused by RSV.

The PRIME initiative, launched by the EMA in 2016, offers early, proactive and enhanced support to developers of promising medicines to optimise development plans and accelerate evaluation so these medicines can reach patients faster. To be eligible for PRIME, medicines must target an unmet medical need and show potential benefit for patients based on early clinical data.

Mene Pangalos, Executive Vice-President, R&D BioPharmaceuticals, said: "We are excited to receive PRIME eligibility for MEDI8897, our next-generation monoclonal antibody targeting respiratory syncytial virus in infants. We will work closely with the European Medicines Agency to optimise our development plan and help us bring MEDI8897 to patients as quickly as possible."

This is the first EMA PRIME eligibility that AstraZeneca has received since the programme's initiation. It is based on the primary analysis of the Phase IIb trial to evaluate the safety and efficacy of MEDI8897, which met its primary endpoint defined as a statistically-significant reduction in the incidence of medically-attended LRTI caused by reverse transcriptase polymerase chain reaction-confirmed RSV for 150 days after dosing in healthy preterm infants. Full results from the Phase IIb trial will be presented at a forthcoming medical meeting.

About MEDI8897
MEDI8897 is an extended half-life RSV F mAb being developed for the prevention of LRTI caused by RSV. MEDI8897 is being developed for use in a broader infant population than the current standard of care for RSV prevention, Synagis (palivizumab), which in the EU is only approved for use in high-risk infants. Additionally, MEDI8897 is being developed so that it may only require one dose during a typical five-month RSV season vs. monthly injections with current standard of care.1

The development programme for MEDI8897 also includes a Phase III trial in late preterm and healthy full-term infants. AstraZeneca will also conduct a Phase II/III study in Synagis-eligible paediatric patients to generate additional data for use in this population.

In March 2017, AstraZeneca and Sanofi Pasteur announced an agreement to develop and commercialise MEDI8897 jointly. In November 2018, AstraZeneca announced Swedish Orphan Biovitrum AB (publ) (Sobi) has the right to participate in payments that may be received from the US profits or losses for MEDI8897.

About RSV

RSV is the most common cause of LRTI in infants and young children worldwide, and 90% of children are infected with RSV in the first two years of life. Of those, up to 40% will experience a LRTI with the initial episode, making the development and availability of effective prevention methods a critical public health priority.2 In the EU, there is currently one approved medicine for RSV prophylaxis, Synagis (palivizumab), indicated for high-risk children (premature infants ≤ 35 weeks gestational age, children with chronic lung disease of prematurity, and children with haemodynamically-significant chronic heart disease).3

About MedImmune

MedImmune is the global biologics research and development arm of AstraZeneca, a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of small molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across Oncology, Respiratory, Cardiovascular, Renal and Metabolic Diseases, and Infection and Vaccines. The MedImmune headquarters is located in Gaithersburg, Md., one of AstraZeneca's three global R&D centres, with additional sites in Cambridge, UK and South San Francisco, CA. For more information, please visit www.medimmune.com.

About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular, Renal & Metabolism and Respiratory. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visitastrazeneca.com and follow us on Twitter @AstraZeneca.

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Adrian Kemp

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AstraZeneca PLC

References

1. Domachowske JB, Khan AA, Esser MT, et al. Safety, Tolerability, and Pharmacokinetics of MEDI8897, an Extended Half-Life Single-Dose Respiratory Syncytial Virus Prefusion F-Targeting Monoclonal Antibody Administered as a Single Dose to Healthy Preterm Infants. The Pediatric Infectious Disease Journal. September 2018:886-892. doi:10.1097/inf.0000000000001916.
2. Adamko DJ, Friesen M. Why does respiratory syncytial virus appear to cause asthma? Journal of Allergy and Clinical Immunology. 2012;130(1):101-102. doi:10.1016/j.jaci.2012.05.024.
3. Synagis Prescribing Information.

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: 05 February 2019

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