

ASTRAZENECA PLC
Form 6-K
February 16, 2017

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 2017

Commission File Number: 001-11960

AstraZeneca PLC

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Cambridge Biomedical Campus
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United Kingdom

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 ☒ 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 ☒

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

16 February 2017, 12 noon GMT

**SILIQ (BRODALUMAB) APPROVED BY THE US FDA
FOR ADULT PATIENTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS**

Approval triggers \$130 million milestone payment to AstraZeneca from
US Partner Valeant Pharmaceuticals

AstraZeneca's partner Valeant Pharmaceuticals today announced that the US Food and Drug Administration (FDA) has approved Siliq (brodalumab) injection for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

Siliq is an IL-17 receptor monoclonal antibody for patients with moderate-to-severe plaque psoriasis, a chronic, debilitating skin disease that causes red patches of skin covered with silvery scales.

Through a collaboration agreement, AstraZeneca granted Valeant, an expert in dermatology, the exclusive license to develop and commercialise Siliq globally, except in Japan and certain other Asian countries where rights are held by Kyowa Hakko Kirin Co., Ltd through an agreement with Amgen, and in Europe, where LEO Pharma holds exclusive rights to develop and commercialise brodalumab through an agreement entered in July 2016.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "We are pleased that our commitment to Siliq, from its development in our biologics pipeline through to our partnership with Valeant, has led to a new treatment option for psoriasis patients, many of whom have previously not been able to achieve full clearance of their skin."

Financial considerations

Under the terms of the agreement, AstraZeneca will receive a milestone payment of \$130 million from Valeant at first regulatory approval. This milestone will be recorded in the AstraZeneca financial statements as Externalisation Revenue. Following the approval, AstraZeneca and Valeant will share profits from the sale of Siliq in the US market.

Marc Dunoyer, Chief Financial Officer, AstraZeneca said: "Our agreement with Valeant supports our externalisation strategy, which allows us to focus on our three main therapy areas while partnering other assets for the benefit of patients, generating sustainable revenue for the future."

- ENDS -

NOTES TO EDITORS

About Siliq

Siliq (brodalumab) is a novel human monoclonal antibody that binds to the interleukin-17 (IL-17) receptor and inhibits inflammatory signalling by blocking the binding of several types of IL-17 to the receptor. By stopping IL-17 from activating the receptor, brodalumab prevents the body from receiving signals that may lead to inflammation. The IL-17 pathway plays a central role in inducing and promoting inflammatory disease processes.

The FDA approval is based on data from the three AMAGINE Phase III pivotal studies that demonstrated that Siliq has an effective mechanism of action that delivers clinical benefit and could help a significant number of moderate-to-severe plaque psoriasis patients achieve total clearance of their skin disease. At the 210mg dose, Siliq was shown to be efficacious in total skin clearance of psoriasis with approximately twice as many patients on Siliq achieving total skin clearance compared to ustekinumab at week 12 in two replicate comparator trials involving over 2,400 patients.

About Valeant

Valeant Pharmaceuticals International, Inc. (NYSE/TSX:VRX) is a multinational specialty pharmaceutical company that develops, manufactures and markets a broad range of pharmaceutical products primarily in the areas of dermatology, gastrointestinal disorders, eye health, neurology and branded generics. More information about Valeant can be found at www.valeant.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 main therapy areas - Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas

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of autoimmunity, neuroscience and infection. 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 and follow us on Twitter @AstraZeneca.

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Adrian Kemp

Company Secretary, AstraZeneca PLC

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: 16 February 2017 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary