GSK announces extension of FDA review period for momelotinib

PUBLISHED JUN 16, 2023
BY GSK

For media and investors only

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has extended the review period of the new drug application (NDA) for momelotinib by three months to provide time to review recently submitted data. The extended action date is 16 September 2023.

GSK is confident in the momelotinib NDA and looks forward to working with the FDA as they finalise their review.

Momelotinib is not currently approved in any market.

Momelotinib has a novel mechanism of action, with inhibitory ability along three key signalling pathways: Janus kinase (JAK) 1, JAK2, and activin A receptor, type I (ACVR1). 1,2,3,4 Inhibition of JAK1 and JAK2 may improve constitutional symptoms and splenomegaly. 1,2,4 Additionally, direct inhibition of ACVR1 leads to a decrease in circulating hepcidin, which is elevated in myelofibrosis and contributes to anaemia. 1,2,3,4

Myelofibrosis is a rare blood cancer that results from dysregulated JAK-signal transducer and activator of transcription protein signalling and is characterised by constitutional symptoms, splenomegaly, and progressive anaemia. Myelofibrosis affects approximately 25,000 patients in the US. 1,5,6

GSK is focused on maximising patient survival through transformational medicines. GSK's pipeline is focused on immuno-oncology, tumour cell targeting therapies and synthetic lethality. Our goal is to achieve a sustainable flow of new treatments based on a diversified portfolio of investigational medicines utilising modalities such as small molecules, antibodies, and antibody-drug conjugates, either alone or in combination.

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com.

Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include but are not limited to those described under Item 3.D 'Risk factors" in the company's Annual Report on Form 20-F for 2022, GSK's Q1 Results for 2023 and any impacts of the COVID-19 pandemic.

Chifotides, HT, Bose, P, Verstovsek, S. Momelotinib: an emerging treatment for myelofibrosis patients with anemia. J Hematol Oncol. 2022;15(7):1-18.

Verstovsek S, et al. MOMENTUM: momelotinib vs danazol in patients with myelofibrosis previously treated with JAKi who are symptomatic and anemic. Future Oncol. 2021;17(12):1449-1458.

Asshoff M, et al. Momelotinib inhibits ACVR1/ALK2, decreases hepcidin production, and ameliorates anemia of chronic disease in rodents. Blood. 2017;129(13):1823-1830.

Oh S, et al. ACVR1/JAK1/JAK2 inhibitor momelotinib reverses transfusion dependency and suppresses hepcidin in myelofibrosis phase 2 trial. Blood Adv. 2020;4(18):4282-4291.

Data on file. Sierra Oncology. 2021.

Naymagon, L, Mascarenhas, J. Myelofibrosis-Related Anemia: Current and Emerging Therapeutic Strategies. HemaSphere. 2017;1(1):e1.

Press release distributed by Wire Association on behalf of GSK, on Jun 16, 2023. For more information subscribe and follow us.

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