US FDA extends review of Bayer's menopause relief drug

The non-hormonal treatment, elinzanetant, is being reviewed for relieving moderate to severe vasomotor symptoms, also known as hot flashes, associated with menopause.

Bengaluru: The U.S. Food and Drug Administration has extended its review of Bayer's experimental menopause relief drug, the German company said on Friday.

The non-hormonal treatment, elinzanetant, is being reviewed for relieving moderate to severe vasomotor symptoms, also known as hot flashes, associated with menopause.

The FDA has extended the review by up to 90 days and did not raise any concern regarding the general approvability of the drug, Bayer said.

The German maker of drugs and agricultural supplies had been counting on new drugs, including elinzanetant, to strengthen its pharmaceuticals business amid declining revenue from its once top-selling blood-thinner Xarelto.

Bayer had been preparing for the market launch of elinzanetant this year, expecting potential peak annual sales of at least $1 billion.

The drug, branded as Lynkuet, was recently approved in the United Kingdom and Canada, with submissions underway in the Eurpean Union.

Japanese drugmaker Astellas' oral drug Veozah, another non-hormonal treatment, is approved in the U.S. for hot flashes associated with menopause.

Bayer's marketing application for elinzanetant was based on data from three late-stage studies in which it reduced the frequency and severity of hot flashes and eased sleep disturbances, improving menopause-related quality of life. (Reporting by Mariam Sunny in Bengaluru; Editing by Alan Barona)

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