

Proactive Group

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FDA reviewing Verastem's potential new leukemia med duvelisib

Biopharmaceutical company Verastem Inc. (NASDAQ:VSTM) announced Monday that the U.S. Food and Drug Administration (FDA) is reviewing its new leukemia drug duvelisib as a potential blood cancer treatment.

The announcement sent Verastem's shares up 16.6% to US\$3.45 in pre-market trade.

FDA target action date is October 5

Boston-based Verastem, which specializes in new cancer drugs, bought duvelisib in 2016 from the original developer Infinity Pharmaceuticals Inc. (NASDAQ:INFI) for \$US28mln.

Duvelisib is an oral inhibitor used for the treatment of chronic lymphocytic leukemia. The company is also seeking an accelerated approval for the treatment of relapsed and obstinate follicular lymphoma which is a type of non-Hodgkin lymphoma.

The FDA target action date is October 5, 2018.

Verastem said obtaining "priority review" in the U.S for duvelisib marked an "important milestone" for the company.

Priority Review is granted by the FDA to drugs that, if approved, would provide significant improvements in the treatment of serious illness.

"As an orally administered therapy, we believe duvelisib will provide an important treatment option for patients with leukemia and small lymphocytic lymphoma and follicular lymphoma," said Robert Forrester, CEO of Verastem.

"We look forward to working with the FDA during the review process. We are continuing our commercial preparations for duvelisib to execute the launch promptly in the U.S. if approved," added Forrester.

The clinical-stage biopharmaceutical company said it was also exploring "ex-U.S. partnering opportunities for duvelisib" and plans to file a European Marketing Application towards the end of 2018.

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