GSK Seeks FDA Approval to Extend Platelet Drug to Hep C Patients

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GlaxoSmithKline (GSK) is seeking approval from the Food and Drug Administration (FDA) to use its thrombocytopenia drug eltrombopag as a treatment for hepatitis C, MedCity News reports.

Eltrombopag—branded as Promacta in the United States and Revolade elsewhere worldwide—is approved in 88 countries to treat thrombocytopenia, a condition in which a person's blood platelet count drops, often as a result of being attacked by his or her own immune system. This can cause uncontrolled bleeding or hemorrhaging.

Interferon—currently a critical element of hepatitis C treatment—is known to depress platelet counts, potentially resulting in thrombocytopenia. As a result, interferon-based therapy is contraindicated for patients who already have low platelet counts. GSK hopes that eltrombopag will help raise platelet counts in such patients, allowing them to start or resume interferon-based therapy. In a Phase III trial that ended in 2011, hepatitis C patients who took eltrombopag along with interferon-based therapy showed an improvement in sustained virologic response.

Potential safety risks for eltrombopag include blood clots, bleeding and liver damage. Until late 2011, the FDA required doctors and patients to watch for these symptoms after discontinuing use of the drug. Those requirements have been relaxed, however, as the FDA has decided that information gathered this way was unlikely to reveal whether these symptoms resulted from eltrombopag or from the thrombocytopenia itself.

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