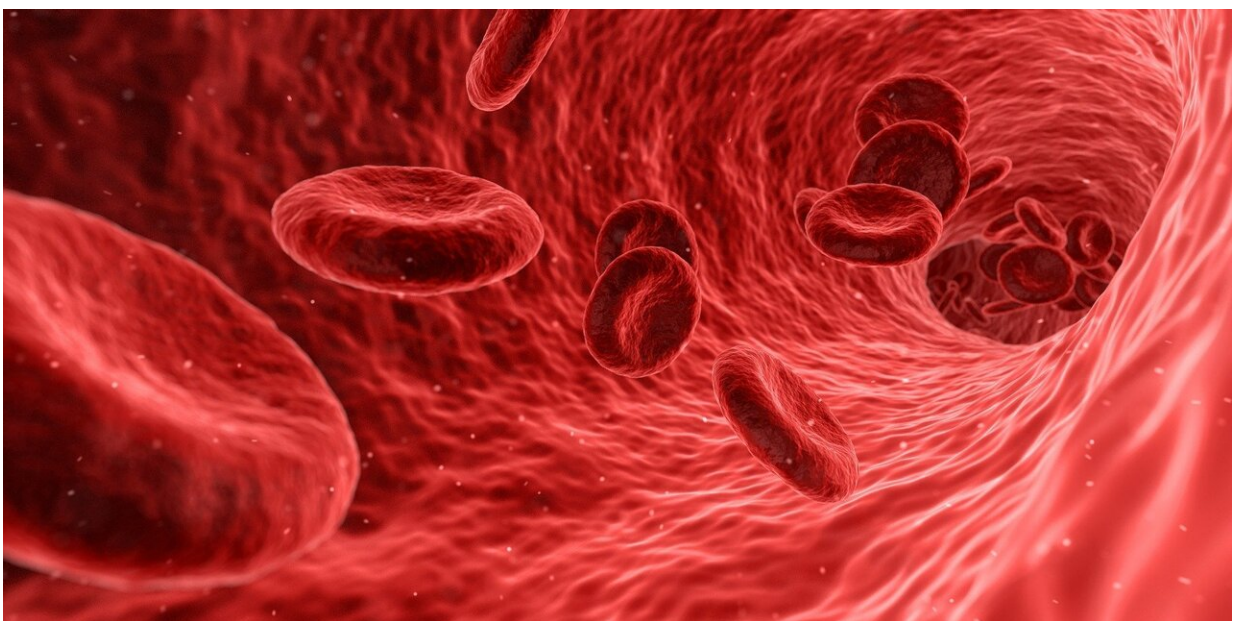


Fostamatinib in chronic immune thrombocytopenia: No comparison—added benefit not proven

October 6 2020



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Fostamatinib is approved for the treatment of chronic immune thrombocytopenia in adults who are refractory to other treatments (in particular to treatment with corticosteroids). The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in an early benefit assessment whether fostamatinib offers an added benefit for these patients in comparison with eltrombopag or romiplostim.

The [drug manufacturer](#) recognized both drugs as appropriate comparator therapy, but presented neither direct nor indirect comparisons between fostamatinib and the appropriate comparator therapy. IQWiG therefore concluded that an added benefit is not proven.

Comparisons with appropriate comparator therapy necessary

The approval studies, the data of which the manufacturer cited in its dossier, compared fostamatinib with placebo. Randomized controlled trials with direct comparisons between fostamatinib and eltrombopag or romiplostim are not available. The manufacturer did not identify any suitable data for an adjusted indirect comparison.

Comparisons with the appropriate comparator [therapy](#) are necessary, however, to understand the benefit and harm that the different treatment options have for the patients in relation to each other. They are the backbone of the early benefit [assessment](#): There is no other way to determine an added benefit of the drug in comparison with the current standard treatment.

G-BA decides on the extent of added benefit

The dossier assessment is part of the early benefit assessment according to the Act on the Reform of the Market for Medicinal Products (AMNOG) supervised by the Federal Joint Committee (G-BA). After publication of the dossier assessment, the G-BA conducts a commenting procedure and makes a final decision on the extent of the added benefit.

More information: www.g-ba.de/english/benefitassessment/

Provided by Institute for Quality and Efficiency in Health Care

Citation: Fostamatinib in chronic immune thrombocytopenia: No comparison—added benefit not proven (2020, October 6) retrieved 4 May 2024 from <https://medicalxpress.com/news/2020-10-fostamatinib-chronic-immune-thrombocytopenia-comparisonadded.html>

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