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Ms Ursula von der Leyen
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Cologne, 23rd July 2024

Open Letter regarding approval of Ocaliva for PBC

Dear Ms von der Leyen, dear Mr Seibert,

we are aware that the European Medicines Agency (EMA) recommended revoking the marketing authorization of Ocaliva (obeticholic acid), used as currently only approved second-line treatment for PBC. The recommendation is now to be decided by the European Commission.

As German's largest liver patients' organization (Deutsche Leberhilfe e.V.), we would like to respectfully ask EC to extend the marketing license for Ocaliva.

While Ocaliva is not an optimal second-line therapy for patients with PBC, it is likely to remain an important treatment option for some patients in the future. As we have heard from numerous patients, Ocaliva has been the only effective therapy despite pre-treatment with UDCA as well as PPAR agonists. This quandary may therefore continue to exist even if new drugs from the class of PPAR agonists such as elafibranor and seladelpar should become available.

Obeticholic acid is the only FXR agonist approved for PBC. According to patient feedback some patients may need three different classes of medications to achieve biochemical remission. Other PBC patients may not respond or be intolerant to PPAR agonists. We are concerned these patients may be left behind and remain undertreated, putting them at risk for progressive liver disease.

As a liver patients' organization and therefore emphasizing and representing patients' interests, we would therefore ask that the availability of Ocaliva be made possible under appropriate conditions, until future developments ensure a comprehensive treatment option for patients with an inadequate response to ursodeoxycholic acid and PPAR agonists.

We thank you for your kind consideration.

With kind regards,

Prof. Christoph Sarrazin MD
Chairman of the Board
Deutsche Leberhilfe e.V. (German Liver Aid)