Clinical and economic value of seladelpar in combination with ursodeoxycholic acid for the treatment of Primary Biliary Cholangitis in Spain

Poster #EE247

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Conclusions

- According to the model results, seladelpar + UDCA may reduce clinical events associated with PBC progression (including decompensated cirrhosis, hepatocellular carcinoma, liver transplantation, and PBC re-emergence) compared with elafibranor + UDCA
- Seladelpar + UDCA reduced disease progression and associated healthcare costs, and may generate substantial cost savings for the Spanish National Health Service (NHS)

Introduction

- Primary biliary cholangitis (PBC) is a rare, cholestatic, and chronic autoimmune disease of the liver that results in the gradual destruction of intrahepatic bile ducts followed by periportal inflammation and cholestasis[1,2,3]
- Seladelpar and elafibranor are approved second-line treatments for PBC. Both interventions have demonstrated substantial efficacy in the Phase III studies RESPONSE[4] and ELATIVE[5], respectively

Objective

- Evaluate the clinical and economic outcomes of seladelpar in combination with ursodeoxycholic acid (UDCA) compared with elafibranor + UDCA in terms of clinical events avoided and associated cost savings in a hypothetical cohort of patients with PBC eligible for second-line (2L) treatment from the Spanish NHS perspective

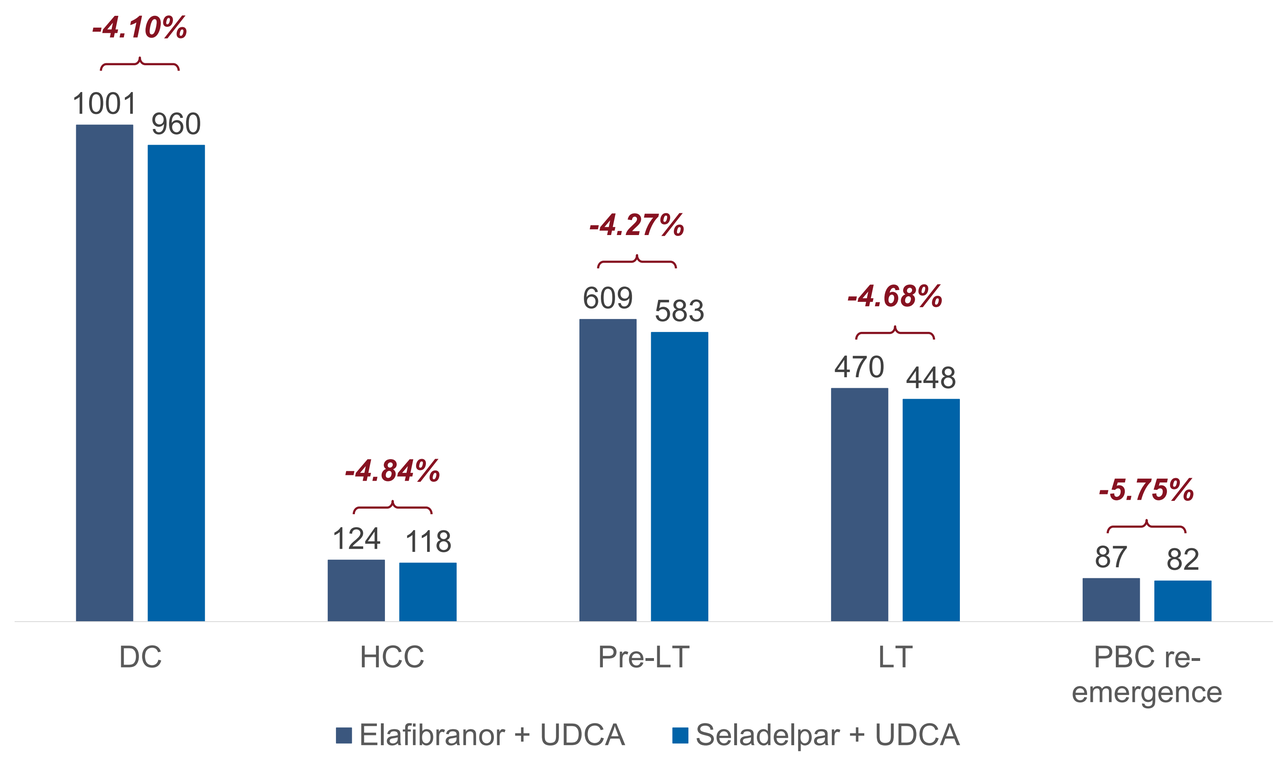
Materials and methods

- A cohort-level Markov state transition model was adapted to reflect the natural history of PBC by simulating liver-related complications (decompensated cirrhosis, hepatocellular carcinoma, pre-transplant, liver transplant) and PBC re-emergence over a lifetime horizon (**Figure 1**)
- Transition probabilities were derived from a matching-adjusted indirect comparison and published literature. Seladelpar was numerically better than elafibranor in most results, including reduction in alkaline phosphatase (ALP) levels and in achieving ALP normalization[6]
- The analysis considered a hypothetical cohort of 3,115 adults eligible for 2L therapy, sourced from published literature (**Figure 2**)[7,8,9,10]
- The analysis focused on downstream liver related complication management-related costs;[11] drug acquisition costs were not included
- A 3% annual discount rate was applied to both costs and outcomes, consistent with economic evaluation guidelines[12]
- All model parameters and assumptions were validated by a multidisciplinary expert panel

Results

- In the hypothetical cohort of 3,115 patients with PBC, seladelpar + UDCA reduced the number of clinical events compared to elafibranor + UDCA (-4.10% decompensated cirrhosis, -4.84% hepatocellular carcinoma, -4.27% pre-transplant, -4.68% liver transplantation, and -5.75% PBC re-emergence) (**Figure 3**)

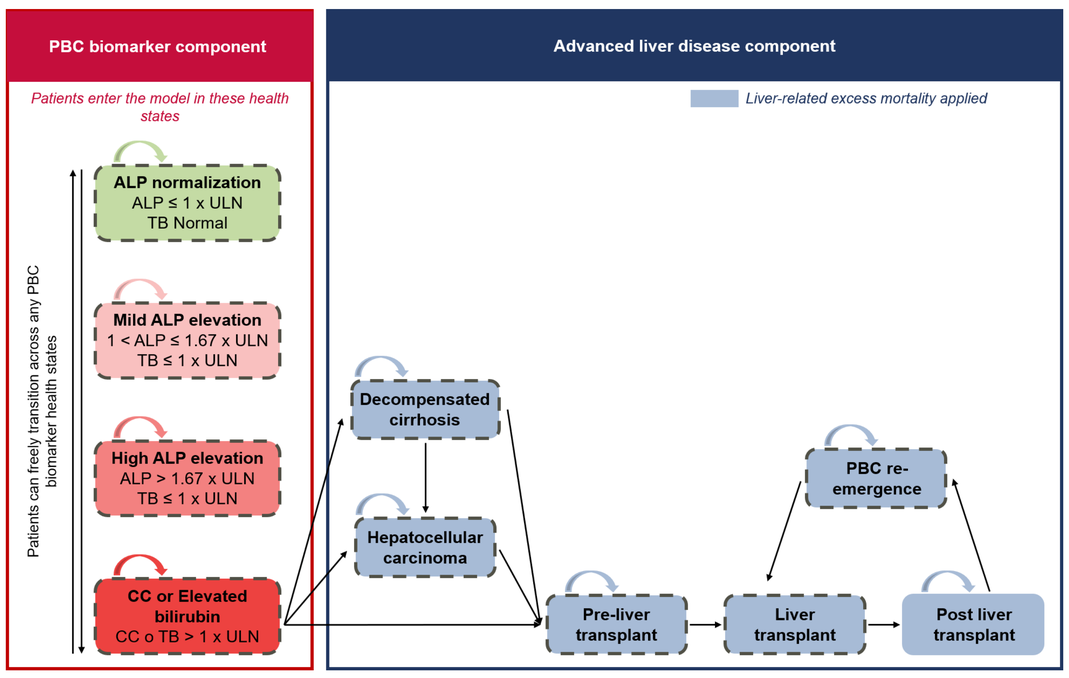
Figure 3. Number of events for each health state by treatment for the cohort of 3,115 patients



DC, decompensated cirrhosis; HCC, hepatocellular carcinoma; LT, liver transplant; PBC, primary biliary cholangitis; pre-LT, pre-liver transplant; UDCA, ursodeoxycholic acid

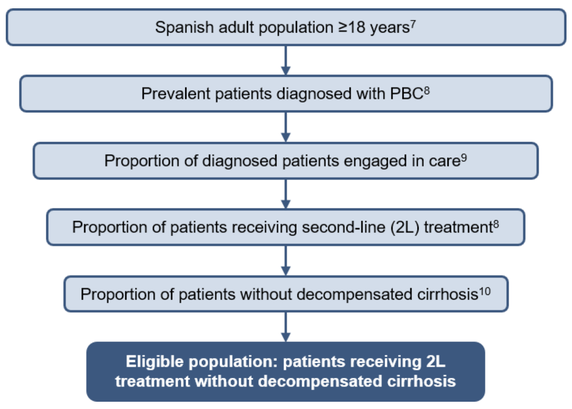
- These reductions translated into €3,561,058 in total cost savings compared to elafibranor + UDCA, associated with managing liver-related complications, including €481,490 for pre-transplant care, €2,546,992 for liver transplantation, and €37,185 for PBC re-emergence (**Figure 4**)

Figure 1. Model structure



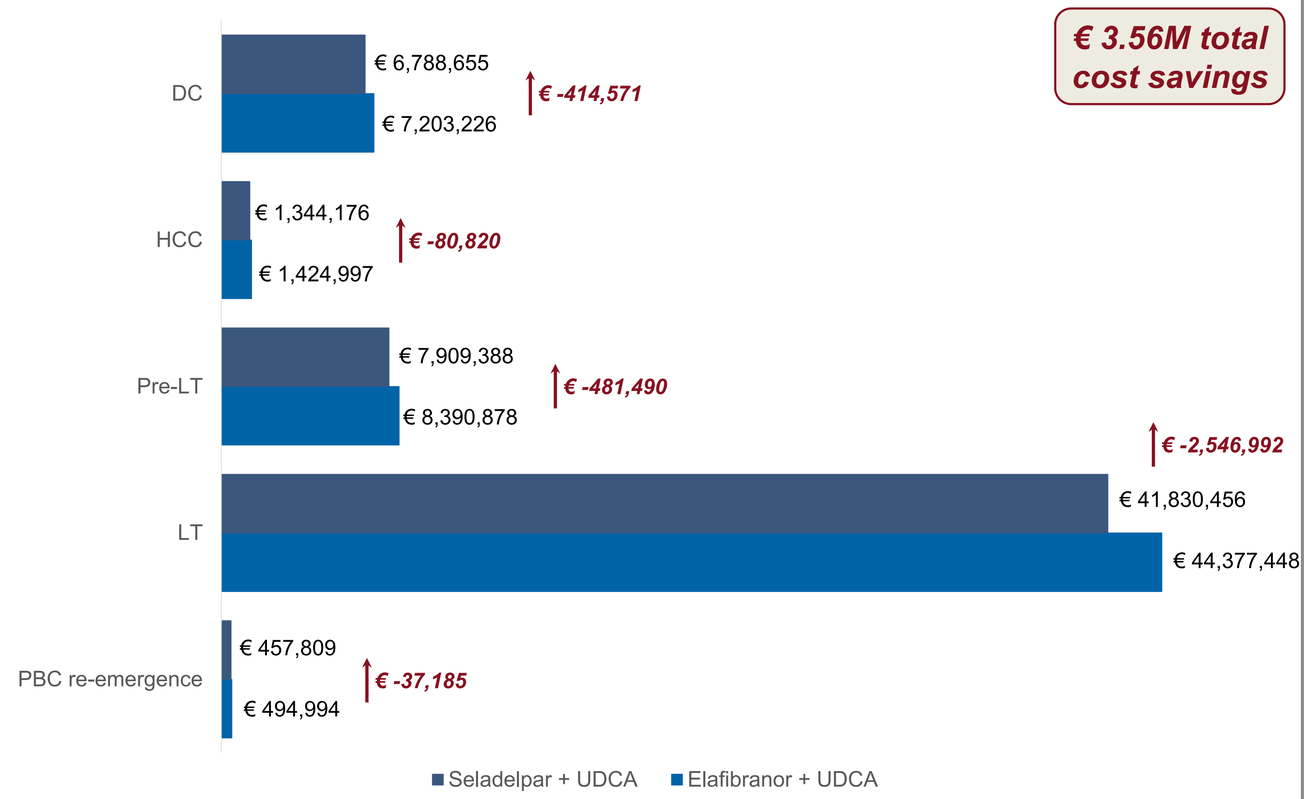
ALP, alkaline phosphatase; CC, compensated cirrhosis; PBC, primary biliary cholangitis; TB, total bilirubin; ULN, upper limit of normal

Figure 2. Target population



PBC, primary biliary cholangitis

Figure 4. Total cost savings for each health state and treatment option for the cohort of 3,115 patients



DC, decompensated cirrhosis; HCC, hepatocellular carcinoma; LT, liver transplant; PBC, primary biliary cholangitis; pre-LT, pre-liver transplant; UDCA, ursodeoxycholic acid

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