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Analyzing Bempedoic Acid's Effectiveness in Treating Hyperlipidemia Clinically

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ABSTRACT

An innovative, first-in-class oral lipid-lowering medication is Bempedoic acid (BA). Since the end of 2020, BA has been commercialized throughout Europe as an add-on therapy for patients with high/very high cardiovascular risk who are not reaching LDL-C goals with existing lipid-lowering medications. BA has received approval from both the European Medicines Agency and the Food and Drug Administration. Italian lipid management experts recently met to discuss several unresolved issues regarding the therapeutic relevance of BA features and BA-related practical clinical issues. The panel agreed to have its thoughts collected in a ten-question format.

Keywords: Bempedoic acid, Hyperlipidemia

INTRODUCTION

An oral, once-daily, small-molecule, first-in-class ACL (Adenosine Triphosphate-Citrate Lyase) inhibitor called Bempedoic acid (BA) blocks this enzyme, which is essential for the pathway that produces cholesterol and works before HMGCR (hydroxymethylglutaryl coenzyme A reductase). The very-long-chain Acyl-CoA synthetase-1 (ACSVL1), which is expressed in the liver but not in skeletal muscle, transforms the pro-drug BA into the active form. The risk of muscle-related side effects with BA is hypothesized to be lower than with statin therapy due to this enzyme's lack of action in skeletal muscle. In addition to activating AMPK, BA also inhibits the formation of hepatic glucose, which is thought to be how it lowers blood sugar levels.

The efficacy and safety characteristics of BA have been established in the 3623 patient CLEAR study. Patients with Atherosclerotic Cardiovascular Disease (ASCVD) and/or HeFH who were taking a maximally tolerated statin experienced a reduction in LDL-C of 17.8% (placebo corrected) and 24.5% (placebo corrected). Regardless of the use and dosage of statins, BA lowered LDL-C by 38.0% (placebo corrected) in a fixed-dose combination with ezetimibe (FDC study). Given the known differences in the action mechanisms of bempedoic acid and ezetimibe, the degree of lipid-lowering supports a combined impact of both drugs. It's interesting to note that 33.7% of patients had an LDL-C reduction of 50% or more from baseline. The LDL-C reduction caused by BA is maintained over a lengthy period. Bempedoic acid reduced LDL-C while also improving total cholesterol, non-HDL-C, apoB, and hs-CRP consistently across many trials.

The most frequent adverse events were comparable to placebo. The difference in the incidence of other adverse events of particular interest between treatment groups was minimal—less than 2%. By blocking the organic anion transporter OAT2, which is involved in the absorption of uric acid and creatinine from the blood into proximal tubular cells, BA may be to blame for slight increases in serum creatinine and uric acid levels. After stopping BA, these effects are stable and fully reversible. Additional pooled studies have revealed that individuals with a history of gout and in particular those with elevated baseline uric acid levels had a

greater gout incidence (above the upper limit of normal). Patients receiving BA had a considerably decreased incidence of diabetes developing for the first time or getting worse.

It is still unknown how BA will affect cardiovascular morbidity and death. In statin-intolerant patients with ASCVD or at high risk of developing ASCVD, the CLEAR-outcomes trial, an ongoing cardiovascular outcomes trial, assesses the effectiveness of BA compared to placebo on the occurrence of MACEs for the first time. The current body of research, according to experts, points to the possibility that BA may have clinical cardiovascular benefits in addition to its LDL-C-reducing effects. The CLEAR-outcomes study findings will aid in proving the cardiovascular advantages of BA therapy.