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OBETICHOLIC ACID (OCALIVATM) APPROVED FOR PRIMARY BILIARY CHOLANGITIS (PBC), LEADING IN THE NASH RACE: HISTORY AND PERSPECTIVES

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Obeticholic acid (OCA), approved in May 2016 by the US FDA for the treatment of primary biliary cholangitis (PBC), is currently the only FDA-designated breakthrough therapy in development for NASH and with the Phase3 trials regenerate and reverse underway is on track to be the first approved drug for a liver disease affecting around 30% of the world population and 70-80% of individuals who are obese and diabetics. The progression from fatty liver/steatosis to nonalcoholic steatohepatitis (NASH) increases the risks for fibrosis, and/or cirrhosis. NASH, projected to become the most common indication for liver transplant in the next decade, is also a risk factor for type 2 diabetes and end stage kidney disease. There are currently no medications approved for the treatment of NASH. In recent years, many drug candidates acting on various pathophysiological NASH processes have entered clinical development. Among the targets, several nuclear receptors, such as FXR and PPARs have shown to have therapeutic potential for the treatment of NASH. The Farnesoid X receptor (FXR), primarily expressed in the liver, gut and liver, plays a key role in bile acids, cholesterol and glucose homeostasis and has been shown to have anti-inflammatory and anti-fibrogenic properties thus representing a suitable therapeutic option for NASH patients. Of all the steroidal and non-steroidal FXR agonists OCA is the most clinically advanced. In this talk, I will summarize the history of OCA for the treatment of PBC, and its current state of development for NASH.