Repositioning for Therapy in Alcoholic and Non-Alcoholic Steatohepatitis

**OCR Number:** OCR 6159

**Description:**

Non-alcoholic steatohepatitis (NASH) is a form of sterile inflammation that is driven by obesity, metabolic syndrome and type 2 diabetes. It can progress to fibrosis, cirrhosis, cancer and death. There are no approved therapies. By 2020, NASH will be the leading cause for liver transplants.

OCR 6159 is an existing drug that:

- Reduces and/or prevents steatosis, liver damage and inflammation in multiple mouse models of liver injury.
- Identified novel target and novel MoA for this drug in the liver.
- Dose-dependent effect. Effective dose is ~1/10<sup>th</sup> - 1/20<sup>th</sup> of the current dose.
- In the High Fat Diet (HFD) model, the effect of OCR 6159 on liver structure and function is comparable to the effect of Obeticholic acid.
- Eligible for accelerated 505(b)(2) FDA pathway.
- **IP status:** PCT National phase filed in 2017 in the US, EP, CN, and CA.
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