



Hope for patients, promise for families.

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Overview

Ocera Therapeutics' lead drug candidate OCR-002 is a novel ammonia scavenger which rapidly removes ammonia from the blood. Elevated ammonia is believed to be a primary cause of hepatic encephalopathy (HE). OCR-002 was recently the subject of a completed Phase 2b trial (STOP-HE) of IV OCR-002, as well as a Phase 1 trial of oral OCR-002. Ocera plans to meet with the FDA in Q3 2017 to discuss paths forward for the IV form and to initiate a Phase 2a multi-dose study in cirrhotic patients in Q2 2017 with a new oral tablet formulation. OCR-002 has received Orphan Drug designation in both the U.S. and Europe and has been granted fast track status by the FDA.

About HE

Hepatic Encephalopathy (HE) is a debilitating and progressive complication of liver cirrhosis, or liver failure, marked by mental changes including confusion, impaired motor skills, disorientation, and in its more severe form, stupor, coma and even death.

Our Mission

Ocera is a clinical stage bio-pharmaceutical company focused on the development and commercialization of novel therapeutics for patients with serious diseases in areas of high unmet medical need.

Products to Treat Acute and Chronic Orphan Liver Diseases

Ocera's drug candidate OCR-002 (ornithine phenylacetate) is a novel and validated ammonia scavenger, designed to treat hyperammonemia (elevated ammonia in the blood) and associated hepatic encephalopathy, a complication of patients with liver cirrhosis or acute liver failure.

When the liver is no longer able to remove toxic substances from the blood, there is an accumulation of such toxins, particularly ammonia. Ammonia accumulation in the blood impairs brain cell function, and can lead to a neuropsychiatric condition called hepatic encephalopathy, or HE.

Product	Formulation	Indication	Preclinical	Phase 1	Phase 2	Phase 3
OCR-002	IV	Acute Hepatic Encephalopathy (HE)*	→			
	Oral	Chronic HE	→			

*FDA Orphan Drug and Fast Track Status

This fact sheet contains forward-looking statements which reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from what is expressed in the forward-looking statements and will be affected by a variety of risks and factors that are beyond our control, including those risks and uncertainties discussed under "Risk Factors" in our Annual Report on form 10-K for the year ended December 31, 2016 as well as other risks detailed in our subsequent filings with the SEC. All information in this summary is as of the date of this document, and we undertake no duty to update this information unless required by law.