Yaqrit prepares phase 3 for ammonia scavenger in hepatic encephalopathy

- Acute and chronic treatment for hepatic encephalopathy acquired from Mallinckrodt Pharmaceuticals in September 2024
- Extended pre-clinical, clinical and IP package includes FDA and EMA orphan drug and FDA fast track designations
- IV formulation to enter phase 3 in 2025; oral formulation to enter phase 2b trials for HE prevention and phase 2a for urea cycle disorders

LONDON, Feb. 11, 2025 (GLOBENEWSWIRE) -- Yaqrit, a late clinical-stage company developing life-saving treatments for advanced liver disease, announced today that its recently acquired ammonia scavenger, L-ornithine phenylacetate (OPA), is progressing to phase 3 for treatment of acute hepatic encephalopathy, a life-threatening complication of decompensated cirrhosis. Development will be via Yaqrit's newly formed subsidiary Amalive Limited, named to reflect the profound impact of ammonia levels in the lives of patients with advanced liver disease.

Amalive is preparing an IV formulation for the phase 3, adapting the trial design based on clinical experience and using AI modelling to guide patient selection. In parallel, Amalive will progress an oral formulation into phase 2b trials for outpatient use in the prevention of HE recurrence. Amalive is also developing an oral liquid formulation to treat and prevent hyperammonaemia associated with urea cycle enzyme disorders, a rare genetic disease that affects children.

"OPA is a key asset for Yaqrit, a potentially great molecule both clinically and commercially, and the creation of subsidiary dedicated to its development will ensure its full potential is realized," said **Troels Jordansen, Chief Executive Officer of Yaqrit**. "For Yaqrit, this also opens the opportunity for further therapeutic and commercial collaborations. With the right partner, we are ready to advance this important treatment into phase 3, building on the accelerated lowering of blood-ammonia already demonstrated in life-threatening HE."

Yaqrit acquired full global rights, including development and commercial, for OPA in any indication from Mallinckrodt Pharmaceuticals in the second half of 2024. Mallinckrodt Pharmaceuticals will receive payments upon the achievement of certain late-stage milestones, plus royalties on sales.

"OPA consolidates Yaqrit's leading position in the development of novel therapies for liver disease," said **Professor Rajiv Jalan, Founder and Chief Medical Officer of Yaqrit**. "OPA addresses ammonia toxicity, a frequent, high-mortality event in vulnerable, advanced liver disease patients. Not only can OPA directly impact the prospects of millions of patients with late-stage liver disease, but it also opens a window for additional interventions in this severely underserved population."

OPA was discovered at the Liver Failure Group, University College London, by Professor Rajiv Jalan, Yaqrit's founder. Earlier development of OPA, including phase 2a and phase 2b studies of both IV and oral forms was undertaken at Ocera Therapeutics, a subsidiary of Mallinckrodt Pharmaceuticals. The available clinical data indicated that OPA reduces levels of toxic ammonia more rapidly than standard of care, facilitating resolution of hepatic encephalopathy, which is one of the most prevalent complications of advanced liver disease[1]. By removing

neurotoxic levels of ammonia from the blood, OPA has the potential to rapidly lower the risk of mortality and multi-organ-failure.

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About Yaqrit

Yaqrit is a clinical-stage company discovering and developing innovative treatments for patients with advanced liver disease at high risk of hospitalization and death. Yaqrit's pipeline includes three novel therapeutics at phase 2-3 of development and two medical devices providing acute and chronic treatments for advanced cirrhosis and acute-on-chronic liver failure where there is an urgent need for more effective treatments. More information is available at www.Yaqrit.com

About Decompensated Cirrhosis

In over 10 million patients worldwide per year, liver cirrhosis progresses from an asymptomatic (compensated) form to the decompensated form at which point the liver can no longer undertake its usual functions. This leads to complications such as jaundice, infections, encephalopathy, ascites and bleeding. The most severe form of decompensation is the occurrence of multiorgan failure, a condition referred to as acute-on-chronic liver failure. These complications lead to increased morbidity with median survival falling from more than 12 years for compensated cirrhosis to about two years for decompensated cirrhosis and less than 3-months for those with multiorgan failure.

About Hepatic Encephalopathy

Hepatic encephalopathy (HE) is a potentially reversible neurological dysfunction associated with excess ammonia in the blood. As many as 40% of decompensated cirrhosis patients are at risk of developing hepatic encephalopathy, with approximately 200,000 patients hospitalized in

the US every year with acute episodes. The recurrence of hepatic encephalopathy is high: a second episode will follow the initial acute event within a year in 40-50% of patients.

[1] OCR002-HE209 Phase 2b Efficacy/safety of Ornithine Phenylacetate in Hospitalized Cirrhotic Patients with Hepatic Encephalopathy