Yaqrit's HE candidates set for phase 3 as company shows underpinning data at EASL

- Improved disease staging tool for hepatic encephalopathy, approved for use by FDA in phase 3 trials of IV ammonia scavenger (YAQ006)
- Dose-response data of oral ammonia scavenger (YAQ007) for prevention of HE recurrence
- In vivo demonstration of ammonia scavenger mechanism of action highlights potential synergistic combination with TLR-4 antagonist (YAQ005)

LONDON, May 7, 2025 (GLOBENEWSWIRE) -- Yaqrit, a late clinical-stage company developing life-saving treatments for advanced liver diseases, is this week revealing data on the progress of both its phase 3 and phase 2b/3 candidate drugs – YAQ006 (IV) and YAQ007 (oral) - for hepatic encephalopathy (HE) at the forthcoming European Association for the Study of the Liver (EASL) Congress, Amsterdam May 7-10th in advance of its clinical trials. Collectively, the data provide an enhanced understanding of the mechanism of action, determine treatment-initiation and endpoints within the HE patient population and define the dosage of YAQ007 (the oral formulation of the ammonia scavenger) to be used for the prevention of recurrence of overt HE.

"EASL 2025 represents a great opportunity for Yaqrit to share data with clinicians and researchers in the liver disease community as we approach late-stage clinical investigation of YAQ006 and YAQ007." said **Troels Jordansen, Yaqrit's Chief Executive Officer**. "There are clear unmet medical needs in advanced liver disease: the EASL presentations demonstrate that Yaqrit is on course to put the right drug in the right patients at the right time and at the right dosage."

YAQ006 and YAQ007 are, respectively, the intravenous and oral formulations of L-ornithine phenylacetate (L-OPA), a potent ammonia-scavenging agent. Yaqrit is preparing to start a phase 3 trial with YAQ006 for hospital treatment of overt HE, a life-threatening complication of decompensated cirrhosis and a phase 2b/3 trial with YAQ007 for outpatient use to prevent recurrence of overt HE.

One key disclosure at EASL is the development of a patient-staging protocol – mHEST (modified Hepatic Encephalopathy Staging Tool). Use of mHEST has been approved by the US Food and Drug Administration (FDA) to evaluate the primary endpoint of 'clinically meaningful improvement' for the phase 3 trial of YAQ006 in patients with overt HE. The strong levels of inter- and intra-rater concordance within mHEST will reduce dependence on subjective assessment and interpretation, helping clinical investigators at various centers make consistent choices in patient selection and endpoint attainment across the trial.

> *Development and validation of the modified hepatic encephalopathy staging tool (mHEST) for grading of hepatic encephalopathy for accurate assessment and regulated clinical trials* (SAT-210). Prof. Rajiv Jalan, Saturday 10th May.

The dose-setting clinical study for YAQ007 (oral formulation of L-OPA) is described in a second EASL presentation. Patients who received 4 g of YAQ007 twice daily showed a decrease in plasma ammonia that was 6 times the decrease seen with rifaximin (550mg twice daily), an antibiotic used

in the current standard treatment for hepatic encephalopathy. There was no significant difference in adverse events.

> *Randomized, open-label, phase 2a comparator study to assess the pharmacodynamics, safety and pharmacokinetics of oral administration of mnk6106 (l-ornithine phenylacetate) vs. rifaximin in subjects with hepatic cirrhosis and a previous history of hepatic encephalopathy* (SAT-209). Prof. Rajiv Jalan, Saturday 10th May.

Transcription and metabolic analysis in mouse models of HE provides evidence that the mode of action of L-OPA may be complementary to that of YAQ005, a TLR4 antagonist, in treating hyperammonemia. This raises the possibility of improved therapeutic strategies in the future.

> *Transcriptomic and metabolic insights into hyperammonemia: the complementary therapeutic roles of toll-like receptor 4 inhibitor and ornithine phenylacetate* (THU-182). Dr. Supachaya Sriphoosanaphan, Thursday 8th May.

“In treating and preventing advanced liver disease with multiple complicating factors in play, there is no substitute for understanding, whether in controlling clinical trial variables or understanding mechanisms of drug action,” said **Professor Rajiv Jalan, Yaqrit’s Founder and Chief Medical Officer**. “These impressive data underpin confidence in the clinical pathway for Yaqrit’s pipeline assets.”

Information on Yaqrit’s eight presentations at EASL 2025 can be found on Yaqrit’s website under latest news.

The full abstracts will be available on the EASL Congress website from 08:30AM CEST on 7th May 2025.

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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 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 over 80,000 patients hospitalized in the US every year with overt episodes. The recurrence of hepatic encephalopathy is high: a second episode will follow the initial overt event within a year in 40-50% of patients.