

# Top liver disease conference showcases positive clinical data from Yaqrit's technologies

Results from two trials presented at EASL<sup>1</sup> International Liver Conference 2021 show benefits for patients with liver failure and those with advanced cirrhosis

**London, UK, 24 June, 2021** – New treatments for liver disease patients have been given top billing at this week's International Liver Congress (ILC), one of the biggest global meetings for liver doctors and researchers, including technologies being developed by Yaqrit Discovery Ltd ('Yaqrit' or the 'Company'), a UK life sciences company developing treatments for patients with cirrhosis and its complications, an area of global unmet medical need.

## Dialive™ is an ICU device for patients suffering from acute-on-chronic liver failure

In the first of two presentations on Yaqrit's Dialive technology, trial data showed that patients had statistically significantly better outcomes when treated with Dialive compared to patients in a control group.

Twice as many patients in the group treated with Dialive resolved from acute on chronic liver failure grades 1, 2 or 3 to ACLF grade 0. The treated group also resolved more quickly than the standard of care group.

**Dr Banwari Agarwal, Chief Investigator and presenter of the data at the ILC, commented**: "To see patients with ACLF grades 1, 2 and 3a resolving to ACLF 0 at twice the rate with Dialive treatment compared to those in the control group, is simply a remarkable outcome. Furthermore, this improvement was achieved with no treatment-related safety issues, which will be vital as the product enters pivotal studies in a larger population of patients."

ACLF is a serious condition often treated in the hospital intensive care unit. Patients have a 28-day expected short term mortality rate that ranges from 20% to over 80%<sup>2</sup>. Dialive is an ICU treatment based on the double filtration of blood-borne toxins and the replacement of damaged circulating albumin.

Carbalive<sup>™</sup> is an orally-administered macroporous carbon bead solution to treat decompensated cirrhosis

Yaqrit's second technology, Carbalive, is an adsorbent taken by mouth by patients with decompensated cirrhosis. Decompensated patients are usually hospitalised and at risk of deteriorating further to life-threatening ACLF.

 $<sup>^{\</sup>rm 1}\,{\rm EASL}$  : European Association For The Study Of The Liver

<sup>&</sup>lt;sup>2</sup> "The systemic inflammation hypothesis: Towards a new paradigm of acute decompensation and multiorgan failure in cirrhosis. Arroyo et al JHEP 2020

Carbalive also met its primary endpoint of safety in a placebo-controlled clinical trial across Europe and in addition showed positive trends in markers of inflammation and gut health. These measures of gut health included those that signify a reduction in the translocation (leaking) of bacterial toxins out of the gut, an important factor in cirrhosis<sup>3</sup>.

**Dr Jane McNaughton, a University College London hepatologist presenting the data at ILC, said** "These findings in decompensated cirrhosis patients pave the way for the next stage of clinical development, which will be to evaluate Carbalive in dedicated efficacy studies and in higher risk patient populations."

The EU Horizon 2020-supported clinical trials of Dialive and Carbalive were conducted in hospitals across Europe respectively by two academic-industrial consortia, ALIVER and CARBALIVE. Both technologies had previously strong preclinical data at University College London, where they had been invented and developed by Professor Rajiv Jalan and colleagues at the Liver Failure Group based at the Royal Free Hospital, London.

**Professor Rajiv Jalan M.D., Professor of Hepatology at UCL, Yaqrit's lead founder, said**, "Carbalive's design is based on many observations of the course of patients in liver decompensation and the damaging inflammation that results. It's pleasing to see that not only has its safety been shown in this study but that there are encouraging signs of benefits to patients, which we hope will be confirmed in future trials."

"The randomised controlled clinical trials conducted with two of Yaqrit's development programmes product candidates yielded promising clinical results, and those obtained with Dialive exceeded our expectations", said Daniel Green, CEO of Yaqrit. "We look forward to expanding our trials globally for both Carbalive and Dialive."

At the International Liver Congress, Dr Agarwal's presentation is:

<u>Session:</u> Global Session – 1997 <u>Date/Time:</u> 24 June 2021, 4 pm CEST <u>Abstract:</u> A multi-centre, randomized controlled study, to evaluate the safety and performance of the DIALIVE Liver Dialysis Device in patients with Acute on Chronic Liver Failure (ACLF) versus standard of care (SOC)

At the International Liver Congress, Dr McNaughtan's presentation is:

<u>Session:</u> PO-1045 <u>Date/Time:</u> 26 June 2021, 9.08 am CEST <u>Abstract:</u> A Double Blind, Randomised, Placebo-Controlled Study To Assess Safety and Tolerability of Oral Enterosorbent Yaq-001 In Cirrhotic Patients (CARBALIVE Consortium)

At the International Liver Congress, Dr Bañares's presentation is:

<u>Session:</u> OS-2060 <u>Date/Time:</u> 26 June 2021, 10.15 am CEST

<sup>&</sup>lt;sup>3</sup> Leaky Gut and Gut-Liver Axis in Liver Cirrhosis: Clinical Studies Update - Fukui et al Gut Liver 2020 https://pubmed.ncbi.nlm.nih.gov/33071239/

<u>Abstract</u>: Pathophysiological basis of resolution of Acute-on-Chronic Liver Failure (ACLF) induced by the novel liver dialysis device, DIALIVE

### About the ALIVER Consortium

The ALIVER consortium includes many of Europe's leading experts in liver failure and the hospitals where they work, small and medium-sized enterprises (SMEs) and not-for-profit organisations, with 25 years of experimental research and data collection exploring extracorporeal liver support in liver failure. DIALIVE research has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733057.For more information visit <u>www.aliver.info</u>

## About the CARBALIVE Consortium

Humans have nearly 10 trillion intestinal bacteria. This is the gut microbiome, which both plays an important role in human health and is the largest reservoir of antigens and bacterial products in the body. If the gut is damaged, as is the case in liver disease, the bacterial products can leak from the gut to the liver where they cause inflammation and injury. These changes happen in chronic liver disease and in cirrhosis. Gut microbes also play a role in the progression of fatty liver disease to advanced liver disease, and it is these challenges that the CARBALIVE consortium was established to address. The Carbalive consortium has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 634579. For more information visit www.carbalive.eu

### About Yaqrit Discovery Ltd

Yaqrit is a clinical stage life sciences company focused on developing innovative treatments for patients with advanced liver disease in areas of high unmet medical need. The Company was founded by internationally renowned hepatologist Professor Rajiv Jalan of UCL, who has three decades of clinical, academic and research experience in treating patients with chronic liver disease. The Company has developed a clinical stage pipeline led by three programs: Carbalive and Dialive, both of which have complete randomised controlled clinical trials, and TLR4 antagonists, the most advanced of which is being developed by Akaza Bioscience, a collaboration with Takeda. These programs are designed to address unmet medical needs across the advanced stages of chronic liver disease from medically stable patients with decompensated cirrhosis in the outpatient setting, to critically ill, hospitalised patients with acute-on-chronic liver failure. The application of the different therapeutic approaches to specific patient groups is based upon the Company's deep understanding of the pathway and stratification of patients with chronic liver disease. For more information visit www.yaqrit.com

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For further information is also available at <u>www.aliver.info</u> and <u>www.carbalive.eu</u>

Disclaimer as of 18 May 2022:

The data relating to CARBALIVE described on the EC website should be considered a "preliminary analysis" and although it is based on a fully audited and monitored Clinical Study, the trial was terminated on March 26th 2020, due to the pandemic preventing patient travel to hospital for mandatory safety assessments. 31 of a possible 58 patients had been enrolled. The 31 patients included the entire cohort taking the lower of two doses. Since treatment of this cohort was completed, the data generated formed the basis of evidence gathered and the conclusions drawn. Further details on the CARBALIVE clinical study outcomes can be found on https://yaqrit.com/news/the-carbalive-consortium-announces-positive-results-of-a-phase-2-equivalent-trial-of-engineered-macroporous-carbons-as-a-novel-treatment-for-cirrhosis/ with details of the clinical study protocol on the ClinicalTrials.gov web site https://clinicaltrials.gov/ct2/show/record/NCT03202498. The results underwent QC review on February 14th 2022 and returned to the sponsor on April 15th 2022 to address any concerns raised. Once these have been addressed, the results will be made public and a copy of the Clinical Study Report will be available on request from the Sponsor: Yaqrit Limited (www.yaqrit.com)

The data relating to ALIVER described on the EC website should be considered a "preliminary analysis" and although it is based on a fully audited and monitored Clinical Study Report, it has not been fully peer reviewed and therefore not published. Further details on the ALIVER clinical study outcomes can be found on https://yaqrit.com/news/the-aliver-consortium-announces-positive-results-from-phase-2-equivalent-trial-of-the-novel-liver-dialysis-device-dialive/ with details of the clinical study protocol on the ClinicalTrials.gov web site https://www.clinicaltrials.gov/ct2/show/study/NCT03065699 and a copy of the Clinical Study Report is available on request from the Sponsor: Yaqrit Limited (www.yaqrit.com).