The ALIVER Consortium announces positive results from Phase 2 equivalent trial of the novel liver dialysis device, Dialive™

- *Safety of novel liver dialysis device confirmed*
- *Liver failure patients in ICU treated with Dialive™ more likely to see organ failure resolved, and more quickly (p=0.03)*
- *Significant improvements in mechanistic biomarkers of how Dialive™ improves organ function*

7th January 2021 – The ALIVER Consortium is pleased to announce positive data from the randomised controlled clinical trial of Dialive™ in adult patients with liver failure. The study found that twice as many patients with a history indicative of alcohol-related cirrhosis suffering from multiorgan failure, a condition referred to as acute-on-chronic liver failure (ACLF), recovered to having no organ failure when treated with the Dialive™ device compared to the control group.

ALIVER is a consortium focused on developing a new treatment for patients with liver failure for whom there are no specific approved therapies apart from liver transplantation. The Consortium is composed of partners from across Europe, led by University College London (UCL), and includes Yaqrit Ltd, a life sciences company and intellectual property owner of Dialive™, the European Foundation for the Study of Chronic Liver Failure (www.efclif.com) and the European Association for the Study of the Liver (www.easl.com) amongst others. The consortium is developing and testing a novel blood filtration system, DIALIVE, whose design is based on 20 years of research led by Professor Rajiv Jalan, Professor Nathan Davies and members of the Liver Failure Group at UCL. Yaqrit Ltd was spun off from UCL in 2014 to develop and potentially commercialise treatments including Dialive™ for patients with advanced liver disease. Professor Jalan is the lead scientific founder of Yaqrit.

Dialive™ is a patented dual filtration system that can be delivered using a kidney dialysis machine. It includes two specialised filters - one to remove blood-borne products of liver failure, such as products of cell death and bacterial toxins, and the other to remove albumin that is damaged and toxic when the liver fails. The damaged albumin is then replaced with fresh albumin.

ACLF is a condition characterised by systemic inflammation and is associated with single or multiple organ failure. The result is a high short-term risk of death. In ACLF patients, 28-day mortality can be as high as 88.9%[i] depending on the number of organs failing.

The safety and tolerability primary endpoints of the randomised controlled trial were met. There were no significant differences in serious adverse events (SAEs) between the control and study group. In addition, more patients receiving Dialive™ treatment resolved to a “no-ACLF” status than the control arm, and they resolved faster (p=0.03). Improvement in the Dialive™-treated patients was also seen in a panel of biomarkers thought to be associated with the cytokine storm and organ failure in ACLF. These showed statistically significant benefits for patients on Dialive™ compared to the control arm, 10 days after the start of the treatment protocol of three to five sessions of eight to 12 hours each. The conclusions set forth in this announcement remain subject to finalising the remaining data analysis, the statistical and clinical study report and, therefore may change.

Professor Rajiv Jalan M.D., Professor of Hepatology at UCL, Founding Member of EASL CLIF, Coordinator of the ALIVER consortium and an inventor of Dialive™, commented: "I am delighted to share these incredibly promising data which indicate that Dialive has the potential to significantly change the outlook for ACLF patients by reversing the course of their disease. Currently, there are no approved therapies for ACLF and around 40% of patients die within three months of hospital admission. We believe Dialive could potentially be a much-needed solution and Yaqrit is planning to further trials to facilitate the product's path to regulatory approval. I acknowledge gratefully the support of the EU H2020 grant, the huge contribution of all our collaborators and the patients who have been instrumental in the progress the Consortium has made in allowing the development of this treatment that has the potential to save the lives of patients with liver failure."

Dr Banwari Agarwal, Consultant Intensivist at Royal Free Hospital and Chief Investigator of the trial, commented: "This is an exciting milestone in the development of a treatment for patients with Acute on Chronic Liver Failure, a culmination of 25 years of work by some of the Consortium's members. We recognise the importance of the funding provided by the EU H2020 grant, which has been paramount in the development of Dialive™ and success of ALIVER. The results will pave the way for Dialive™ to progress to later phase clinical trials."

Prof. Rafael Bañares of the School of Medicine, Universidad Complutense and Hospital General Universitario Gregorio Marañón, Madrid said: "The consortium was established to develop new therapies which could offer solutions to patients who currently have very few options. The data from this study highlights the potential of Dialive™ to do just this and we look forward to seeing this novel approach get to patients as quickly as possible."

The ALIVER Consortium has received funding from the European Union's Horizon 2020 research and innovation programme. Yaqrit, the Dialive™ intellectual property and commercial rights holder and member of the ALIVER consortium, intends to conduct a randomised European pivotal trial in 2021. Plans are also underway to pursue a U.S. regulatory pathway.

Full results from the trial will also be submitted for peer reviewed publication in a leading scientific journal.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733057.

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About DIALIVE

DIALIVE is a novel liver failure treatment device designed to reverse the accumulation of protein-bound toxins and increased susceptibility to infection caused by liver failure, for which liver transplantation is the main alternative treatment. The DIALIVE device, protected by worldwide patents, incorporates albumin removal and replacement and, endotoxin removal. The device is being studied in clinical trials in patients with acute on chronic liver failure (ACLF) up to grade 3a (up to three organs in failure).

About ALIVER

The ALIVER consortium includes many of Europe's leading of experts in liver failure and the hospitals where they work, small and medium-sized enterprises (SMEs) and not-for-profit organisations, with over 20 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 www.aliver.info

About Yaqrit

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. With his guidance, 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 joint venture with Takeda Pharmaceutical and Zenios Bioscience. 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 ("ACLF"). 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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disclosure and ongoing information, the consortium does not intend, and does not assume any obligation, to update forward-looking statements.

[i] Arroyo V, Moreau R, Jalan R. Acute-on-Chronic Liver Failure. N Engl J Med. 2020 May 28;382(22):2137-2145.