Hep-Art completed EU Horizon 2020 program (SME Instrument phase 1) granted project:

The HepaRG-Bio-Artificial Liver: Feasibility of commercialization and expansion of business plan: BALXPAND

End-stage liver disease patients have insufficient mass of functional liver, due to different causes as intoxication, and liver infections. Within a few weeks, their condition can deteriorate to such extent that only 20%-50% of the patients survive. In the Western world, there is an incidence of 0.29-0.41 per 10.000 patients per year. Emergency liver transplantation is the only life-saving therapy, even though this invasive procedure is associated with considerable mortality and morbidity and requires lifelong medicinal immunosuppression. The health care costs for patients that undergo a transplantation are huge: ±120 k€ for the transplantation and 10 k€/yr. per patient for medical immunosuppression. Treatment of morbidities associated with liver transplantation requires intensive care treatment and this will further raise health care costs for end-stage liver patients.
Due to a shortage of donor livers, more than 30,000 patients are on the liver transplant waiting list in Europe and the US. Strikingly, each year, there are only about 12,000 donor livers available in these regions and the average waiting time of patients on the waiting list is 115 days in Europe and 232 days in the US. A significant share of the patients die while being placed on the waiting list. An even larger share of patients suffers from the effects of late transplantation because, while waiting before reaching the criteria for liver transplantation and subsequent availability of a donor liver, their condition worsens and morbidity and mortality after transplantation will increase. There is no treatment available to reverse the disease progress substantially and prevent transplantation.
The SME Hep-Art has, together with academic partners, developed a BAL, named HepaRG-AMCBAL, which is a bioreactor embedded with HepaRG cells, from a human liver stem cell line, that mature to high level inside the BAL. This HepaRG-AMC-BAL is developed to treat the plasma of the end-stage liver disease patients and temporarily replace liver function to bridge the period towards transplantation, or to support liver restoration until transplantation will become superfluous.
A preclinical test showed that the HepaRG-AMC-BAL-prototype treatment provided effective liver support during liver failure.
The overall objective of the project was to prepare the HepaRG-AMC-BAL for a clinical trial to eventually test the safety and efficacy of this treatment modality. To that means Hep-Art aimed to improve the production of cells for the HepaRG-AMC-BAL, obtain insight into the production costs of the HepaRG-AMC-BAL in the clinical implementation phase, to map suitable Contract Manufacturing Organisations (CMOs) with cleanroom production facilities for producing quality tested HepaRG-AMC-BALs, and to develop a feasibility plan with the results of the study.