

Nyberg Final Report

The animal testing portion of our study was completed July 2017. Analysis of cytokine markers of regeneration is expected to be completed in the next month (end of October 2017) and this will define formal completion of the study. All three Specific Aims of the study were accomplished with positive results (enhanced liver regeneration, prolonged survival, neuroprotective benefit of supportive therapy), so the study is considered a resounding success! All of the funds from the Minnesota Regenerative Medicine grant were spent in developing the animal model of post-resection acute liver failure (ALF) and studying the effect of supportive therapy on these pigs in a randomized prospective trial. We ran \$30,000 over budget to complete analysis of the cytokine markers of liver regeneration, so additional funding was secured from the Mayo Regenerative Medicine Program to complete the study.

We will be giving an invited oral presentation of our study at the Presidential Plenary session of The Liver Meeting (AASLD annual meeting) October 24 2017.

Along with this oral presentation we are preparing two manuscripts at this time.

The first manuscript is a model development paper explaining the 85% hepatectomy model of post-resection acute liver failure (ALF) in pigs that was developed and used in the study. The second manuscript will detail the study, a preclinical pivotal randomized prospective trial titled – “Mayo Spheroid Reservoir Bioartificial Liver Improves Survival and Promotes Liver Regeneration in Post Hepatectomy Acute Liver Failure (ALF) Pigs.”

The results of the pivotal preclinical trial will be included in our FDA IND filing. We are currently meeting with investors to secure the \$3-6million in next stage funding. These funds will be used to build (1-3) clinical liver support device(s) and initiate Phase 1 clinical testing. A Minnesota-based start-up company named Liver Cell Technologies has been formed to commercial the technology which is based on I.P. used in this study.

I will forward copies of our two manuscripts to RMM when they have been published.