

## RMB Therapy: A Systems-Biology Approach to mCRC Refractory to Standard Therapies, Phase IIb Data

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American mortality due to colorectal cancer is on the rise, surpassing 50000 in 2018. Advances in systemic therapy have improved the outlook for mCRC patients, nevertheless additional treatment approaches are needed for individuals who despite all progress. The present abstract offers a summary of the RMB (RENCA mouse renal adenocarcinoma cells entrapped in agarose macrobeads) phase IIb trial in the treatment of mCRC patients, its results, and progress made.

In this study 41 heavily pre-treated mCRC patients underwent RMB laparoscopic intraperitoneal implantation (4 times, 8 RMB/kg body weight). Lab Profiles, physical examinations, imaging (PET/CT) were performed pre-/post-implant. OS was the primary endpoint (from time of study entry until death).

Two groups of patients: responders (n=23), non-responders (n=18) were defined by >20% decrease in CEA (mean R Baseline=122.45; Day14=59.311 vs. mean NR Baseline = 1610.31; Day 14 = 1790.23 [p<0.000041]) and/or CA19-9 (mean R Baseline =161.85; Day 14 = 64.69 vs. mean NR Baseline = 949.38889; Day 14 =1930.78 [p< 0.037901]) values. PET-CT analysis showed: 11/18 (61%) SUVmax responders were also TMS responders. We observed 48% reduction in SUVmax (3 necrosis), 25% disease stabilization. Of the 20 LDH responders, 12 were also SUVmax and/or TM responders. Survival was compared between RMB treated, best-supportive care patients & TAS-102(RECOURSE trial results). Data showed median OS of 9.25 months vs.7 weeks vs. 7.2 months, respectively.

The aim of RMB therapy is to increase survival while maintaining maximum quality of life for the mCRC population. A phase III randomized study is in preparation to further assess results.

**Keywords:** Cancer Systems Biology, Gastrointestinal Cancer, Cell-Based Therapeutics, Colorectal Cancer Treatment, Solid Tumors.

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