Journal of Clinical Oncology, 2010 ASCO Annual Meeting Proceedings (Post-Meeting Edition).
Vol 28, No 15_suppl (May 20 Supplement), 2010: 2546

A phase I/II study of intravenous Rexin-G and Reximmune-C for cancer immunotherapy: The GeneVieve protocol.

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Background: Rexin-G (R-G) and Reximmune-C (R-C) are tumor-targeted retrovectors bearing a cytocidal cyclin G1 "knockout" construct and a controllable GM-CSF expression construct, respectively. The hypothesis underlying this two-pronged approach is that the personalized vaccination of a patient against his/her own specific cancer can be achieved by combining (1) a targeted vector bearing a tumoricidal payload, i.e., R-G with (2) a targeted vector bearing a potent immunostimulatory gene, i.e., R-C. Purpose: To evaluate the safety and potential antitumor activity of intravenous infusions of R-G followed by Reximmune-C pulses in chemoresistant solid tumors.

Methods: All patients with chemoresistant pancreas cancer (n=2), colon cancer (n=2), breast cancer (n=1), ovarian cancer (n=1), Ewing's sarcoma (n=1), or prostate cancer (n=1) had achieved a partial response (PR) or stable disease (SD) with prior R-G monotherapy. Eight patients received R-G, 2 x 10e11 cfu on days 1, 3, and 5, plus R-C, 0.5 or 1.0 x 10e10 cfu (dose I or II respectively) on day 3, and valacyclovir at 3 gms/day p.o. on days 6-19, comprising one cycle. Treatment cycles were repeated up to 6 cycles, if there was ≤grade 1 toxicity.

Results: There were no treatment-related adverse events. Table below shows the tumor responses, progression-free survival (PFS), and overall survival (OS) of treated patients. Histopathologic examination of a resected indicator cervical lymph node following treatment showed complete effacement of the lymph node architecture by tumor-infiltrating lymphocytes.

Conclusions: These findings indicate that the GeneVieve protocol is safe and well-tolerated and that this strategic combination of R-G plus Reximmune-C may help control tumor growth and prolong survival—advancing personalized cancer vaccination as a realistic goal.

Reximmune-C dose level	Tumor response by RECIST	Median PFS by RECIST (months)	Median OS (months from start of R-G treatment)
I (n=5)	1 PR, 3 SD, 1 PD	> 9	> 10
II (n=3)	1 PR, 2 SD	> 6	> 8

Author Disclosure

Employment or Leadership Position	Consultant or Advisory Role	Stock Ownership	Honoraria	Research Funding	Expert Testimony	Other Remuneration
Epeius Biotechnologies	Epeius Biotechnologies	Epeius Biotechnologies		Epeius Biotechnologies		

Abstract presentation from the 2010 ASCO Annual Meeting