

Application Number: TRAN4-15225

Presentation to ICOC by Irv Weissman MD October 26, 2023

Our CIRM grant application was deemed not fundable by the GWG. The reviewers stated that CD34 selection is already available and supplies blood stem cells [HSC], implying there is no need for our highly purified, rare, CD34+90+ HSC.

Patients with metastatic breast cancer often have breast cancer cells in the bone marrow. We showed that CD34 selection from breast cancer patients **does not deplete** cancer cells, while our isolated CD34+90+ HSC are cancer-free [see figure].

In 1988 I formed a company, SyStemix, where we isolated pure human HSC .

In clinical trials from 1996-1998 at Stanford we tested purified HSC to rescue blood formation in metastatic breast cancer patients after massive doses of chemotherapy . *The purified cancer-free HSC rapidly regenerated blood formation.* We compared the outcomes in patients rescued with cancer-free HSC with those rescued with mobilized blood . Half the patients rescued with *unpurified cells* were dead by 2 years, while half of the HSC rescued patients were still alive at 10 years. At ~12-14 years all of the patients rescued with unpurified cells were dead or had cancer relapse, *while 33% of the patients rescued with cancer-free HSC were and now are alive*

Giving back cancer to hi dose chemo patients leads to cancer relapse.

I negotiated with the pharma that bought SyStemix for the rights for Stanford to isolate HSC, and bring them into clinical trials in a **not for profit** setting. The first trial will repeat and extend the breast cancer study. This will likely save lives, lower the costs for care, and restore their contributions to their families and to society.

We also discovered that healthy donor purified HSC, lacking T cells, can regenerate blood disease recipients *without graft vs host disease caused by T cells*; CD34 selection still has T cells.

We have also shown that pure HSC transplants induce transplant tolerance to organ grafts from the HSC donors, a one time intervention saving medical costs and lives.

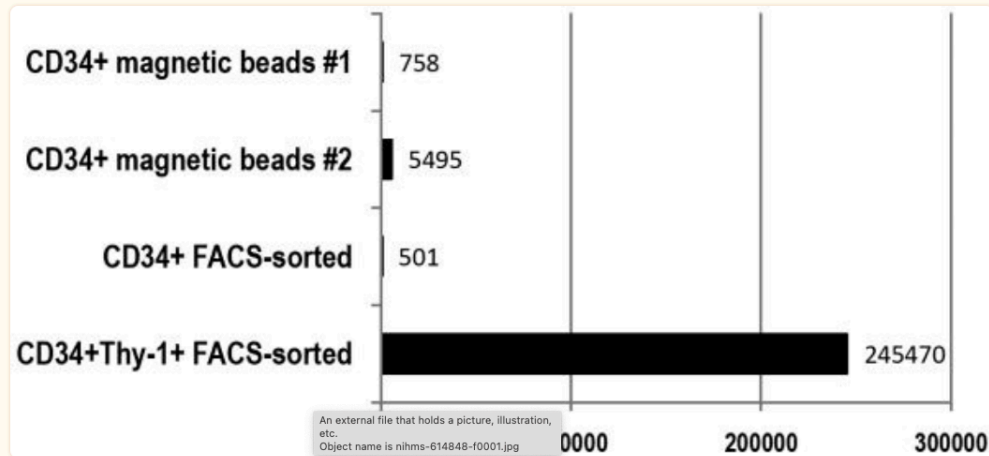
The CIRM GWG did not address or report these facts.

I urge you bring purified blood stem cells finally to therapies for patients with no other chance for cure.

This is an enormous unmet need.. .

Irv Weissman

Fold reduction of breast cancer cells by sorting



[Figure 1](#)

Comparison of fold depletion of cancer cells from MPB using CD34 with and without Thy-1 as positive selecting markers for high-speed cell sorting (FACS) as compared with CD34 magnetic bead selection at MPB. MPB products were purposefully contaminated with tumor cells and the selected products were analyzed by an immunofluorescence (IFM) assay for breast cancer.

[Back to T](#)

[Biol Blood Marrow Transplant. 2012 Jan; 18\(1\): 125–133.](#)

Published online 2011 Jul 20. doi: [10.1016/j.bbmt.2011.07.009](https://doi.org/10.1016/j.bbmt.2011.07.009)

PMCID: PMC4113088NIHMSID: NIHMS614848PMID: [21767515](https://pubmed.ncbi.nlm.nih.gov/21767515/) Long-term Outcome of Patients with Metastatic Breast Cancer Treated with High-Dose Chemotherapy and Transplantation of Purified Autologous Hematopoietic Stem Cells

[Antonia M.S. Müller](#), M.D.,^a [Holbrook E.K. Kohrt](#), M.D.,^b [Steven Cha](#), M.D.,^b [Ginna Laport](#), M.D.,^a [Jared Klein](#), M.D.,^c [Alice E. Guardino](#), M.D.,^b [Laura J. Johnston](#), M.D.,^a [Keith E. Stockerl-Goldstein](#), M.D.,^d [Elie Hanania](#), M.D.,^e [Christopher Juttner](#), MBBS, FRACP,^f [Karl G. Blume](#), M.D.,^a [Robert S. Negrin](#), M.D.,^a [Irving L. Weissman](#), M.D.,^g and [Judith A. Shizuru](#), M.D. Ph.D.^{a,g}

Using self cancer-free blood stem cell transplantation to treat women with metastatic breast cancer

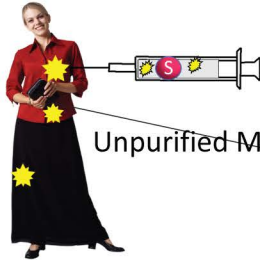
Muller, Juttner, Kohrt, Shizuru, Negrin, Blume Weissman, et al
1996-98, published BBMT 2012

ALL PATIENTS GIVEN VERY HIGH DOSE COMBINATION CHEMOTHERAPY TO KILL MORE CANCER

Cisplatin, cytoxan, carmustine

The problem

Rescue blood system with unpurified graft; giving **cancer back**



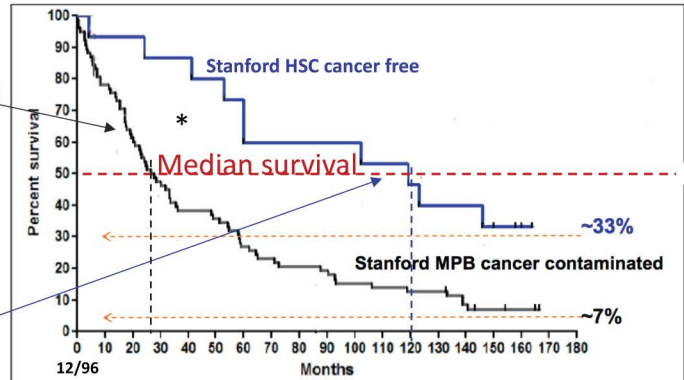
Unpurified MPB

The solution

Rescue with **purified cancer free stem cells**



CD34+90+
From MPB



Median survival: **2 yrs** vs. **10 yrs** with purified stem cells
Overall survival: **7%** vs **33%** with purified stem cells

~160,000 women in US with metastatic breast cancer

Estimated MBC remaining after chemo < 100K.

GMP antiCD34 & antiD90 available In nonprofit setting only:

* Contact irv@stanford.edu for information and participation in future clinical trial