

### Summary and Conclusion

The results of these studies are summarized in the table below.

Table 7

Summary of the Data Reported on Depletion of T Cells from Bone Marrow and Peripheral Blood after Selection with the CEPRATE SC

Reference	Source of Stem Cells (N=number of patients)	Number of CD3+ Cells Prior to Selection	Number of CD3+ Cells After Selection	Number of Logs of T-Cell Depletion
Unpublished Studies	PBSC (9) <sup>†</sup>	$16.1 \times 10^9$	$21.4 \times 10^6$	2.96
	BM (12)	$1.4 \times 10^9$	$3.9 \times 10^6$	2.63
Cottler-Fox	PBSC (11) <sup>‡</sup>	$9.6 \times 10^9$	$8.6 \times 10^6$	3.05
	BM (10)	$5.6 \times 10^9$	$0.8 \times 10^6$	3.85
Link	PBSC (20) <sup>‡</sup>	$3.0 \times 10^{10}$	$2.5 \times 10^7$	3.08
DiPersio	PBSC (6)	Not reported	Not reported	3.0
Schreiner	PBSC (6) <sup>‡</sup>	$157 \times 10^8$	$0.6 \times 10^8$	2.4
Schiller	PBSC(12) <sup>♦</sup>	Not reported	$0.76 \times 10^6$	2-3 <sup>2</sup>

These results support the conclusion that the CEPRATE SC can be used to deplete 2.5 to 3.0 logs of T cells in either bone marrow or mobilized peripheral blood.

<sup>†</sup> Data reported as mean

<sup>‡</sup> Data reported as median

<sup>2</sup> Reported in abstract, not calculated value

## References

- <sup>1</sup> O'Reilly RJ, Keever CA, Small TN, et al (1990) The use of HLA nonidentical T cell depleted marrow transplants for the correction of severe combined immunodeficiency disease. *Immunodef Rev* 1:272.
- <sup>2</sup> Voogt PJ, Fibbe WE, Marjit WAF, et al (1990) Rejection of bone marrow graft by recipient-derived cytotoxic T lymphocytes against minor histocompatibility antigens. *Lancet* 335:131.
- <sup>3</sup> Goldman JM, Gale RP, Horowitz MM, et al (1988) Bone marrow transplantation for chronic myelogenous leukemia in chronic phase: increased risk for relapse associated with T cell-depletion. *Ann Intern Med* 108:806.
- <sup>4</sup> To LB, Roberts MM, Haylock DN et al. (1992) Comparison of haematological recovery times and supportive care requirements of autologous phase peripheral blood stem cells transplants, autologous bone marrow transplants and allogeneic bone marrow transplants. *Bone Marrow Transplant* 9:277.
- <sup>5</sup> Wagner JE, Santos GW, Noga SJ et al (1990) Bone marrow graft engineering by counterflow centrifugal elutriation: results of a phase I-II clinical trial. *Blood* 75:1370.
- <sup>6</sup> Cottler-Fox M, Cipolone K, Yu M, et al (1995) Positive selection of CD34+ hematopoietic cells using an immunoaffinity column results in T cell-depletion equivalent to elutriation. *Experimental Hematology* 23: 320.
- <sup>7</sup> Arseniev J, Kadar JG, Berenson RJ, et al (1995) Allogeneic peripheral blood progenitor cell mobilization, collection and immunoselection. EBMT, Davos, Switzerland, 1995.
- <sup>8</sup> Link H, Arseniev L, Bahre O, et al. Transplantation of immunoaffinity selected allogeneic peripheral blood CD34+ cells alone or in addition to bone marrow. 9th Symposium Molecular Biology of Hematopoiesis. Genoa, Italy, 1995.
- <sup>9</sup> Schiller G, Buckner CD, Berenson R, et al. Transplantation of allogeneic CD34+ peripheral blood stem cells (PBSC) in patients with advanced hematologic malignancy. ASH. Seattle. 1993.
- <sup>10</sup> DiPersio J, Martin B, Abboud C, et al. Allogeneic BMT using bone marrow and CD34- selected mobilized PBSC: comparison to BM alone and mobilized PBSC alone. ASBMT, Keystone, Colorado, 1995.
- <sup>11</sup> Schreiner T, Wiesneth M, Friedrich W, et al. Allogeneic PBPC grafts for HLA-nonidentical transplantation: combination of CD34+ selection and T-cell depletion.