



## Reference list

# MACS® GMP ExpAct Treg Kit

## Performance/ Expansion data

### **A Rapamycin-based GMP Compatible Process for the Isolation and Expansion of Regulatory T cells for Clinical Trials**

Fraser H., Safinia N., Grageda N., Thirkell S., Lowe K., Fry L., Scotta C., Hope A., Fisher C., Hilton R., Game D., Harden P., Bushell A., Wood K., Lechler R.I., Lombardi G.

Molecular Therapy Methods and Clinical Development (2018)

### **Good Manufacturing Practice-Compliant Production and Lot-Release of Ex Vivo Expanded Regulatory T Cells As Basis for Treatment of Patients with Autoimmune and Inflammatory Disorders.**

Wiesinger M., Stoica D., Roessner S., Lorenz C., Fischer A., Atreya R., Neufert C. F., Atreya I., Scheffold A., Schuler-Thurner B., Neurath M. F., Schuler G. and Voskens C. J.

Front. Immunol. (2017) 8:1371. doi: 10.3389/fimmu.2017.01371

### **Characterization and Expansion of Autologous GMP-ready Regulatory T Cells for TREG-based Cell Therapy in Patients with Ulcerative Colitis.**

Voskens C.J., Fischer A., Roessner S., Lorenz C., Hirschmann S., Atreya R., Neufert C., Atreya I., Neurath M., Schuler G.

Inflamm Bowel Dis (2017) 23:1348–1359

### **Clinical-Grade Expanded Tregs Prevent GvHD While Allowing a Powerful T-Cell Dependent GvL Effect in Murine Models.**

Del Papa B, Ruggeri L, Urbani E, Baldoni S, Cecchini D, Zei T, Iacucci Ostini R, Crescenzi B, Carotti A, Pierini A, Sportoletti P, Di Bartolomeo P, Falzetti F, Mecucci C, Velardi A, Martelli MF, Di Ianni M.

Biology of Blood and Marrow Transplantation (2017)

### **GMP validation of large-scale expansion of regulatory T cells from patients affected by liver and kidney failure.**

C. Lavazza, M. Viganò, T. Montemurro, E. Montelatici, S. Budelli, M. G. Cannone, S. Savelli, F. Ulbar, L. Catani, V. Giudice, M. Cescon, G. La Manna, R. M. Lemoli, R. Giordano.

ISCT Meeting (2017) poster presentation

### **Utilization of leukapheresis and CD4 positive selection in Treg isolation and the ex-vivo expansion for a clinical application in transplantation and autoimmune disorders.**

Gołąb K., Grose R., Trzonkowski P., Wickrema A., Tibudan M., Marek-Trzonkowska N., Matosz S., Solomina J., Ostrega D., Millis J. M., Witkowski P.

Oncotarget. (2016) Nov 29; 7(48): 79474–79484.

**A robust, good manufacturing practice–compliant, clinical-scale procedure to generate regulatory T cells from patients with amyotrophic lateral sclerosis for adoptive cell therapy.** Alsuliman, A., Appel, S.H., Beers, D.R., Basar, R., Shaim, H., Kaur, I., Zulovich, J., Yvon, E., Muftuoglu, M., Imahashi, N., Kondo, K., Liu, E., Shpall, E.J., Rezvani, K. Cytotherapy. (2016) Oct;18(10):1312-24

**Successful expansion of functional and stable regulatory T cells for immunotherapy in liver transplantation.** Safinia N, Vaikunthanathan T, Fraser H, Thirkell S, Lowe K, Blackmore L, Whitehouse G, Martinez-Llordella M, Jassem W, Sanchez-Fueyo A, Lechler RI, Lombardi G. Oncotarget. (2016) Jan 17.

**Adoptive transfer of allogeneic regulatory T cells into patients with chronic graft-versus-host disease.**

Theil A, Tuve S, Oelschlägel U, Maiwald A, Döhler D, Oßmann D, Zenkel A, Wilhelm C, Middeke JM, Shayegi N, Trautmann-Grill K, von Bonin M, Platzbecker U, Ehninger G, Bonifacio E, Bornhäuser M. Cytotherapy. (2015) Apr;17(4):473-86.

**Clinical-grade separation and expansion of regulatory T cells for clinical studies on cell therapy in solid organ transplantation.** Fazekasova H., Thirkell, S. Lowe K., Bushell A., and Lombardi G. MACS&more Vol 15 – 2/2013

**Clinical scale enrichment and expansion of highly pure CD25+FoxP3 regulatory T cells.** Conrads, C., Schmitz, J., Assenmacher, M., Niemand, C., Scheffold, A. ASH Meeting, (2010), Poster abstract 3718.

**Clinical-grade regulatory T cells: Comparative analysis of large scale expansion conditions.** Velaga, S., Alter, C., Dringenberg, U., Thiesler, C.T., Kuhs, S., Olek, S., Ukena, S.N., Franzke, A. Experimental Hematology (2016) Sep 27. pii: S0301-472X(16)30620-8



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