



## ***Product-Related Bibliography***

---

### **Manuscripts**

#### **2018**

Matthay MA, Calfee CS, Zhuo H, Thompson BT, Wilson JG, Levitt JE, Rogers AJ, Gotts JE, Wiener-Kronish JP, Bajwa EK, Donahoe MP, McVerry BJ, Ortiz LA, Exline M, Christman JW, Abbott J, Delucchi KL, Caballero L, McMillan M, McKenna DH, Liu KD. Treatment with allogeneic mesenchymal stromal cells for moderate to severe acute respiratory distress syndrome (START study): a randomised phase 2a safety trial. *The Lancet*. 2018. Epub 2018 Nov 16. [http://dx.doi.org/10.1016/S2213-2600\(18\)30418-1](http://dx.doi.org/10.1016/S2213-2600(18)30418-1).

Keller CA, Gonwa TA, Hodge DO, Hei DJ, Centanni JM, Zubair AC. Feasibility, Safety, and Tolerance of Mesenchymal Stem Cell Therapy for Obstructive Chronic Lung Allograft Dysfunction. *Stem Cell Transl Med*. 2018 Jan 11. doi: 10.1002/sctm.17-0198. [Epub ahead of print]. [PMID: 29322685]

#### **2017**

McKenna DH Jr, Sumstad D, Kadidlo DM, Batdorf B, Lord CJ, Merkel SC, Koellner CM, Curtsinger JM, June CH, Riley JL, Levine BL, Miller JS, Brunstein CG, Wagner JE, Blazar BR, Hippen KL. Optimization of cGMP purification and expansion of umbilical cord blood-derived T-regulatory cells in support of first-in-human clinical trials. *Cytotherapy*. 2017 Feb;19(2):250-262. doi: 10.1016/j.jcyt.2016.10.011. Epub 2016 Nov 22. [PMID: 27887864]

#### **2016**

Taylor DA, Perin EC, Willerson JT, Zierold C, Resende M, Carlson M, Nestor B, Wise E, Orozco A, Pepine CJ, Henry TD, Ellis SG, Zhao DX, Traverse JH, Cooke JP, Schutt RC, Bhatnagar A, Grant MB, Lai D, Johnstone BH, Sayre SL, Moyé L, Ebert RF, Bolli R, Simari RD, Cogle CR; Cardiovascular Cell Therapy Research Network (CCTRN). Identification of Bone Marrow Cell Subpopulations Associated With Improved Functional Outcomes in Patients With Chronic Left Ventricular Dysfunction: An Embedded Cohort Evaluation of the FOCUS-CCTRN Trial. *Cell Transplant*. 2016;25(9):1675-1687. Epub 2015 Nov 19. [PMID: 26590374]

Bartlett RS, Guille JT, Chen X, Christensen MB, Wang SF, Thibeault SL. Mesenchymal stromal cell injection promotes vocal fold scar repair without long-term engraftment. *Cytotherapy*. 2016 Oct;18(10):1284-96. doi: 10.1016/j.jcyt.2016.07.005. [PMID: 27637759]

Naik S, Nicholas SK, Martinez CA, Leen AM, Hanley PJ, Gottschalk SM, Rooney CM, Hanson IC, Krance RA, Shpall EJ, Cruz CR, Amrolia P, Lucchini G, Bunin N, Heimall J, Klein OR, Gennery AR, Slatter MA, Vickers MA, Orange JS, Heslop HE, Bollard CM, Keller MD. Adoptive immunotherapy for primary immunodeficiency disorders with virus-specific T lymphocytes. *J Allergy Clin Immunol*. 2016 May;137(5):1498-1505.e1. doi: 10.1016/j.jaci.2015.12.1311. [PMID: 26920464]

Braun, RK, Koch JM, Hacker TA, Pegelow D, Kim J, Raval AN, Schmuck EG, Schwahn DJ, Hei DJ, Centanni JM, Eldridge M, Hematti P. Cardiopulmonary and histological characterization of an acute rat lung injury model demonstrating safety of mesenchymal stromal cell infusion. *Cytotherapy*. 2016 Apr; 18(4): 536–545. doi: 10.1016/j.jcyt.2016.01.010. [PMID: 26971682].

Bartlett RS, Guille JF, Chen X, Christensen MB, Wang SF, Thibeault SL. Mesenchymal stromal cell injection promotes vocal fold scar repair without long-term engraftment. *Cytotherapy*. 2016 Oct; 18(10): 1284–1296. doi: 10.1016/j.jcyt.2016.07.005. [PMID: 27637759].



Schmuck EG, Koch JM, Centanni JM, Hacker TA, Braun RK, Eldridge M, Hei DJ, Hematti P, Raval AN. Biodistribution and Clearance of Human Mesenchymal Stem Cells by Quantitative Three-Dimensional Cryo-Imaging After Intravenous Infusion in a Rat Lung Injury Model. *Stem Cells Trans Med.* 2016 Dec; 5(12):1668-1675. Epub 2016 Jul 26. [PMID: 27460855].

## **2015**

Chen VC, Ye J, Shukla P, Hua G, Chen D, Lin Z, Liu JC, Chai J, Gold J, Wu J, Hsu D, Couture LA. Development of a scalable suspension culture for cardiac differentiation from human pluripotent stem cells. *Stem Cell Res.* 2015 Sep;15(2):365-75. Epub 2015 Aug 13. [PMID: 26318718].

Sun J, Huye LE, Lapteva N, Mamonkin M, Hiregange M, Ballard B, Dakhova O, Raghavan D, Durett AG, Perna SK, Omer B, Rollins LA, Leen AM, Vera JF, Dotti G, Gee AP, Brenner MK, Myers DG, Rooney CM. Early transduction produces highly functional chimeric antigen receptor-modified virus-specific T-cells with central memory markers: a Production Assistant for Cell Therapy (PACT) translational application. *J Immunother Cancer.* 2015 Feb 18;3:5. [PMID: 25734008].

Bloom DD, Centanni JM, Bhatia N, Emler CA, Drier D, Levenson GE, McKenna, Jr. DH, Gee AP, Lindblad R, Hei DJ, Hematti P. A reproducible immunopotency assay to measure mesenchymal stromal cell-mediated T-cell suppression. *Cytotherapy.* 2015 17(2):140-51. doi: 10.1016/j.jcyt.2014.10.002. [PMID: 25455739]

Schmuck EG, Koch JM, Hacker TA, Hatt CR, Tomkowiak MT, Vigen KK, Hendren N, Leitzke C, Zhao Y, Li Z, Centanni JM, Hei DJ, Schwahn D, Kim J, Hematti P, Raval AN. Intravenous Followed by X-ray Fused with MRI-Guided Transendocardial Mesenchymal Stem Cell Injection Improves Contractility Reserve in a Swine Model of Myocardial Infarction. *J of Cardiovasc Trans Res.* 2015; 8(7):438-448. doi:10.1007/s12265-015-9654-0. [PMID: 26374144].

## **2014**

Hacein-Bey-Abina S, Pai S-Y, Gaspar HB, Armant M, Berry CC, Blanche S, Bleesing J, Blondeau J, de Boer H, Buckland KF, Caccavelli L, Cros G, De Oliveira S, Fernández KS, Guo D, Harris CE, Hopkins G, Lehmann LE, Lim A, London WB, van der Loo JCM., Malani N, Male F, Malik P, Marinovic MA, McNicol A-M, Moshous D, Neven B, Oleastro M, Picard C, Ritz J, Rivat C, Schambach A, Shaw KL, Sherman EA, Silberstein LE, Six E, Touzot F, Tsytsykova A, Xu-Bayford J, Baum C, Bushman FD, Fischer A, Kohn DB, Filipovich AH, Notarangelo LD, Cavazzana M, Williams DA, and Thrasher AJ. A modified  $\gamma$ -retrovirus vector for X-linked severe combined immunodeficiency. *N Engl J Med.* 2014; 371(15):1407-17. doi: 10.1056/NEJMoa1404588. [PMID: 25295500].

Pollock K, Sumstad D, Kadidlo D, McKenna D, and Hubel A. Clinical mesenchymal stromal cell products undergo functional changes in response to freezing. *Cytotherapy.* 2015. 17(1):38-45. doi: 10.1016/j.jcyt.2014.06.008. [PMID: 25457275].

Wright LS, Phillips JM, Pinilla I, Hei D, and Gamm DM. Induced pluripotent stem cells as custom therapeutics for retinal repair: progress and rationale. *Exp Eye Res.* 2014. 123:161-72. doi: 10.1016/j.exer.2013.12.001. Epub 2014 Feb 16. [PMID: 24534198].

Raval AN, Schmuck EG, Tefera G, Leitzke C, Ark CV, Hei D, Centanni JM, de Silva R, Koch J, Chappell RG, and Hematti P. Bilateral administration of autologous CD133+ cells in ambulatory patients with refractory critical limb ischemia: lessons learned from a pilot randomized, double blind, placebo-controlled trial. *Cytotherapy.* 2014. Dec;16: 1720-1732.[PMID: 25239491].

Kharbanda S, Smith AR, Hutchinson SK, McKenna DH, Ball JB, Lamb LS, Agarwal R, Weinberg KI and Wagner JE. Unrelated donor allogeneic hematopoietic stem cell transplantation for patients with hemoglobinopathies using a reduced-intensity conditioning regimen and third-party mesenchymal stromal cells. *Biol Blood Marrow Transplant.* 2014 Apr;20(4):581-6. [PMID: 24370862].



- Bajgain P, Mucharla R, Wilson J, Welch D, Anurathapan U, Liang B, Lu X, Ripple K, Centanni J, Hall C, Hsu D, Couture LA, Gupta S, Gee AP, Heslop HE, Leen AM, Rooney CM and Vera JF. Optimizing the production of suspension cells using the G-Rex "M" series. *Molecular Therapy - Methods and Clinical Development*. 2014. Epub 2014 May 14. Article number: 14015. doi:10/1038/mtm.2014.15
- Hanley PJ, Mei Z, Durett AG, Cabreira-Harrison M, Klis M, Li W, Zhao Y, Yang B, Parsha K, Mir O, Vahidy F, Bloom D, Rice BR, Hematti P, Savitz SI, and Gee AP. Efficient manufacturing of therapeutic mesenchymal stromal cells with the use of the Quantum Cell Expansion System. *Cytotherapy*. 2014 Aug;16(8):1048-58. [PMID: 24726657].
- Papadopoulou A, Gerdemann U, Katari U, Tzannou I, Liu H, Martinez C, Leung K, Carrum G, Gee AP, Vera JF, Krance RA, Brenner MK, Rooney CM, Heslop HE and Leen AM. Activity of broad-spectrum T cells as treatment for AdV, EBV, CMV, BKV and HHV6 infections after HSCT. *Sci Transl Med*. 2014 Jun 25;6(242):ra83. [PMID: 24964991].
- Papadopoulou A, Krance RA, Allen CE, Lee D, Rooney CM, Brenner MK, Leen AM, and Heslop HE. Systemic inflammatory response syndrome after administration of unmodified T lymphocytes. *Mol Ther*. 2014 Jun;22(6):1134-8. [PMID: 24651135].
- Lapteva N, Szmania SM, VanRhee F, and Rooney CM. Clinical grade purification and expansion of Natural Killer cells. *Crit Rev Oncog*. 2014;19(1-2):121-32. [PMID: 24941378].
- McAuley DF, Curley GF, Hamid UI, Laffey JG, Abbott J, McKenna DH, Fang X, Matthay MA, and Lee JW. Clinical grade allogeneic human mesenchymal stem cells restore alveolar fluid clearance in human lungs rejected for transplantation. *Am J Physiol Lung Cell Mol Physiol*. 2014 May 1;306(9):L809-15. doi: 10.1152/ajplung.00358.2013. Epub 2014 Feb 14. [PMID: 24532289].
- Bollard CM, Gottschalk S, Torrano V, Diouf O, Ku S, Hazrat Y, Carrum G, Ramos C, Fayad L, Shpall EJ, Pro B, Liu H, Wu MF, Lee D, Sheehan AM, Zu Y, Gee AP, Brenner MK, Heslop HE, and Rooney CM. Sustained complete responses in patients with lymphoma receiving autologous cytotoxic T lymphocytes targeting Epstein-Barr virus latent membrane proteins. *J Clin Oncol*. 2014 Mar 10;32(8):798-808. doi: 10.1200/JCO.2013.51.5304. Epub 2013 Dec 16. [PMID: 24344220].
- Leen AM, Heslop HE, and Brenner MK. Antiviral T-cell therapy. *Immunol Rev*. 2014 Mar;258(1):12-29. [PMID: 24517423].
- Rooney CM, Leen AM, Vera JF, and Heslop HE. T lymphocytes targeting native receptors. *Immunol Rev*. 2014 Jan; 257(1):39-55. [PMID: 24329788].
- Sawitzki B, Brunstein C, Meisel C, Schumann J, Vogt K, Appelt C, Curtsinger JM, Verneris MR, Miller JS, Wagner JE, and Blazar BR. Prevention of Graft-versus host disease by adoptive T regulatory therapy is associated with active repression of peripheral blood toll-like receptor 5 mRNA expression. *Biol Blood Marrow Transplant*. 20 (2014) 173-182. [PMID: 24184334].

## **2013**

- Gerdemann U, Keukens L, Keirnan JM, Katari UL, Nguyen CT, de Pagter AP, Ramos CA, Kennedy-Nasser A, Gottschalk SM, Heslop HE, Brenner MK, Rooney CM, and Leen AM. Immunotherapeutic strategies to prevent and treat human herpesvirus 6 reactivation after allogeneic stem cell transplantation. *Blood*. 2013; 121:207-218. [PMID: 23152545].



- Gerdemann U, Katari UL, Papadopoulou A, Keirnan JM, Craddock JA, Liu H, Martinez CA, Kennedy-Nasser A, Leung KS, Gottschalk SM, Krance RA, Brenner MK, Rooney CM, Heslop HE, and Leen AM. Safety and clinical efficacy of rapidly-generated trivirus-directed T cells as treatment for Adenovirus, EBV and CMV infections after allogeneic hematopoietic stem cell transplant. *Mol Ther*. 2013; 21(11):2113-21. [PMID: 23783429].
- Brunstein CG, McKenna DH, DeFor TE, Sumstad D, Paul P, Weisdorf DJ, Ratajczak M, Laughlin MJ, and Wagner JE. Complement fragment 3a priming of umbilical cord blood progenitors: safety profile. *Biol Blood Marrow Transplant*. Published online 2013 July 26; 19:1474-9. [PMID: 23892047].
- Leen AM, Bollard CM, Mendizabal AM, Shpall EJ, Szabolcs P, Antin JH, Kapoor N, Pai S, Rowley SD, Kebriaei P, Dey BR, Grilley BJ, Gee AP, Brenner MK, Rooney CM, and Heslop HE. Multicenter study of banked third party virus-specific T-cells to treat severe viral infections after hematopoietic stem cell transplantation. *Blood*. June 2013; 121(26):5113-5123. [PMID: 23610374].
- Hanley PJ, Mei Z, da Graca Cabreira-Hansen M, Klis M, Li W, Zhao Y, Durett AG, Zheng X, Wang Y, Gee AP and Horwitz EM. Manufacturing mesenchymal stromal cells for phase I clinical trials. *Cytotherapy*. 2013 Apr;15(4):416-422. [PMID: 23480951].
- Lee JW, Krasnodembskaya A, McKenna DH, Song Y, Abbott J, and Matthay MA. Therapeutic effects of human mesenchymal stem cells in *ex vivo* human lungs injured with live bacteria. *Am J Respir Crit Care Med*. 2013 Jan 4 187(7):751-760. Epub ahead of print. [PMID: 23292883].
- Klingemann H, Grodman C, Cutler E, Duque M, Kadidlo D, Klein AK, Sprague KA, Miller KB, Comenzo RL, Kewalramani T, Yu N, Van Etten RA, and McKenna DH. Autologous stem cell transplant recipients tolerate haploidentical related-donor natural killer cell-enriched infusions. *Transfusion*. 2013; 53(2):412-18. Epub 2012 June 28. [PMID: 22738379].
- Koepsell SA, Kadidlo DM, Fautsch S, McCullough J, Klingemann H, Wagner JE, Miller JS, and McKenna DH. Successful "in-flight" activation of natural killer cells during long-distance shipping. *Transfusion*. 2013; 53(2):398-403. Epub 2012 May 10. [PMID: 22574659].
- Zimmerlin L, Rubin JP, Pfeifer ME, Moore LR, Donnenberg VS, and Donnenberg AD. Human adipose stromal vascular cell delivery in a fibrin spray. *Cytotherapy*. 2013; 15:102-108. [PMID: 23260090].
- 2012**
- Perin EC, Willerson JT, Pepine CJ, Henry TD, Ellis SG, Zhao DXM, Silva GV, Lai D, Thomas JD, Kronenberg MW, Martin AD, Anderson RD, Traverse JH, Penn MS, Anwaruddin S, Hatzopoulos AK, Gee AP, Taylor DA, Cogle CR, Smith D, Westbrook L, Chen J, Handberg E, Olson RE, Geither C, Bowman S, Francescon J, Baraniuk S, Piller LB, Simpson LM, Loghin C, Aguilar D, Richman S, Zierold C, Bettencourt J, Sayre SL, Vojvodic RW, Skarlatos SI, Gordon DJ, Ebert RF, Kwak M, Moye LA, and Simari RD. Effect of transendocardial delivery of autologous bone marrow mononuclear cells on functional capacity, left ventricular function, and perfusion in chronic heart failure: the FOCUS-CCTRN trial. *JAMA*. 2012 Apr 25;307(16):1717-26. Epub 2012 Mar 24. [PMID: 22447880].
- Sili U, Leen AM, Vera JF, Gee AP, Huls H, Heslop HE, Bollard CM, and Rooney CM. Production of good manufacturing practice-grade cytotoxic T lymphocytes specific for Epstein-Barr virus, cytomegalovirus and adenovirus to prevent or treat viral infections post-allogeneic hematopoietic stem cell transplant. *Cytotherapy*. 2012. 14:7-11. [PMID: 22172091].
- Gerdemann U, Keirnan JM, Katari UL, Yanagisawa R, Christin AS, Huye LE, Perna SK, Ennamuri S, Gottschalk S, Brenner MK, Heslop HE, Rooney CM, and Leen AM. Rapidly generated multivirus-specific cytotoxic T lymphocytes for the prophylaxis and treatment of viral infections. *Mol Ther*. 2012 Aug; 20(8):1622-32. [PMID: 22801446].



Traverse JH, Henry TD, Pepine CJ, Willerson JT, Zhao DXM, Ellis SG, Forder JR, Anderson RD, Hatzopoulos AK, Penn MS, Perin EC, Chambers J, Baran KW, Raveendran G, Lambert C, Lerman A, Simon D, Vaughan DE, Lai D, Gee AP, Taylor DA, Cogle CR, Thomas JD, Olson RE, Bowman S, Francescon J, Geither C, Handberg E, Kappenman C, Westbrook L, Piller L, Simpson LM, Baraniuk S, Loghin C, Aguilar D, Richman S, Zierold C, Spoon DB, Bettencourt J, Sayre SL, Vojvodic RW, Skarlatos SI, Gordon DJ, Ebert RF, Kwak M, Moye LA, and Simari RD. Effect of the use and timing of bone marrow mononuclear cell delivery on left ventricular function after acute myocardial infarction: the TIME randomized trial. *JAMA*. 2012;308(22):2380-2389. [PMID: 23129008].

## **2011**

- Giannoukakis N, Phillips B, Finegold D, Harnaha J, and Trucco M. Phase I (safety) study of autologous tolerogenic dendritic cells in type 1 diabetic patients. *Diabetes Care*. 2011; Sep; 34(9):2026-32. [PMID: 2168720].
- Bollard CM, Gottschalk S, Huls MH, Leen AM, Gee AP and Rooney CM. Good manufacturing practice-grade cytotoxic T lymphocytes specific for latent membrane proteins (LMP)-1 and LMP2 for patients with Epstein-Barr virus-associated lymphoma. *Cytotherapy*. 2011; 13: 518-522. [PMID: 21361747].
- Hippen KL, Merkel SC, Schirm DK, Sieben CM, Sumstad D, Kadidlo DM, McKenna DH, Bromberg JS, Levine BL, Riley JL, June CH, Scheinberg P, Douek DC, Miller JS, Wagner JE, and Blazar BR. Massive ex vivo expansion of human natural regulatory T cells (T(regs)) with minimal loss of in vivo functional activity. *Sci Transl Med*. 2011 May 18;3(83):83ra41. doi: 10.1126/scitranslmed.3001809. [PMID: 21593401].
- Brunstein CG, Miller JS, Cao Q, McKenna DH, Hippen KL, Curtsinger J, DeFor T, Levine BL, June CH, Rubinstein P, McGlave PB, Blazar BR, and Wagner JE. Infusion of ex vivo expanded T regulatory cells in adults transplanted with umbilical cord blood: safety profile and detection kinetics. *Blood*. 2011 Jan 20; 117(3):1061-1070. [PMID: 20952687].
- Cox CS Jr., Baumgartner JE, Harting MT, Worth LL, Walker PA, Shah SK, Ewing-Cobbs L, Hasan KM, Day MC, Lee D, Jimenez F, and Gee AP. Autologous Bone Marrow Mononuclear Cell Therapy for Severe Traumatic Brain Injury in Children. *Neurosurgery*. 2011; 68(3):588-600. [PMID: 21192274].
- Savitz SI, Misra V, Kasam M, Juneja H, Cox CS Jr, Alderman S, Aisiku I, Kar S, Gee A, and Grotta JC. Intravenous autologous bone marrow mononuclear cells for ischemic stroke. *Ann Neurol*. 2011 Jul; 70(1):59-69. doi: 10.1002/ana.22458. [PMID: 21786299].
- Gerdemann U, Katari U, Christin AS, Cruz CR, Tripic T, Rousseau A, Gottschalk SM, Savoldo B, Vera JF, Heslop HE, Brenner MK, Bollard CM, Rooney CM, and Leen AM. Cytotoxic T lymphocytes simultaneously targeting multiple tumor-associated antigens to treat EBV negative lymphoma. *Mol Ther*. 2011.Dec;19(12):2258-2268. Epub 2011 Sep 13. [PMID: 21915103].
- Gerdemann U, Vera JF, Rooney CM, and Leen AM. Generation of multivirus-specific T cells to prevent/treat viral infections after allogeneic hematopoietic stem cell transplant. *J Vis Exp*. 2011 May 27;(51). [PMID: 21654628].
- Hanley PJ, Shaffer DR, Cruz CR, Ku S, Tzou B, Liu H, Demmler-Harrison G, Heslop HE, Rooney CM, Gottschalk S, and Bollard CM. Expansion of T cells targeting multiple antigens of cytomegalovirus, Epstein-Barr virus and adenovirus to provide broad antiviral specificity after stem cell transplantation. *Cytotherapy*. 2011; 13:976-986. [PMID: 21539497].



Traverse JH, Henry TD, Ellis SG, Pepine CJ, Willerson JT, Zhao DX, Forder JR, Byrne BJ, Hatzopoulos AK, Penn MS, Perin EC, Baran KW, Chambers J, Lambert C, Raveendran G, Simon DI, Vaughan DE, Simpson LM, Gee AP, Taylor DA, Cogle CR, Thomas JD, Silva GV, Jorgenson BC, Olson RE, Bowman S, Francescon J, Geither C, Handberg E, Smith DX, Baraniuk S, Piller LB, Loghin C, Aguilar D, Richman S, Zierold C, Bettencourt J, Sayre SL, Vojvodic RW, Skarlatos SI, Gordon DJ, Ebert RF, Kwak M, Moyé LA, and Simari RD; Cardiovascular Cell Therapy Research Network. Effect of intracoronary delivery of autologous bone marrow mononuclear cells 2 to 3 weeks following acute myocardial infarction on left ventricular function: the Late TIME randomized trial. *JAMA*. 2011; 306, 2110-2119. [PMID: 22084195].

## **2010**

Melenhorst JJ, Leen AM, Bollard CM, Quigley MF, Price DA, Rooney CM, Brenner MK, Barrett AJ, and Heslop HE. Allogeneic virus-specific T cells with HLA alloreactivity do not produce GVHD in human subjects. *Blood*. 2010; 116(22):4700-2. [PMID: 20709906].

Vera JF, Brenner LJ, Gerdemann U, Ngo MC, Sili U, Liu H, Wilson J, Dotti G, Heslop HE, Leen AM, and Rooney CM. Accelerated production of antigen-specific T-cells for preclinical and clinical applications using Gas-permeable Rapid Expansion cultureware (G-Rex). *J Immunother*. 2010 Apr; 33(3):305-15. [PMID: 20445351].

Matthay MA, Thompson BT, Read EJ, McKenna DH, Liu KD, Calfee CS, and Lee JW. Therapeutic potential of mesenchymal stem cells for severe acute lung injury. *Chest*. 2010; 138(4):965-72. [PMID: 20923800].

Donnenberg VS, Zimmerlin L, Rubin JP, and Donnenberg AD. Regenerative therapy after cancer: what are the risks? *Tissue Eng Part B Rev*. 2010; 16:567-575. [PMID: 20726819].

El Khoury R, Misra V, Sharma S, Cox CS, Walker P, Grotta JC, Gee AP, Suzuki S, and Savitz SI. The effect of transcatheter injections on cell viability and cytokine release of mononuclear cells. *AJNR Am J Neuroradiol*. 2010; 31:1488-1492. [PMID: 20395386].

Szczepanski MJ, Szajnik M, Welsh A, Foon KA, Whiteside TL, and Boyiadzis M. Interleukin-15 enhances natural killer cell cytotoxicity in patients with acute myeloid leukemia by upregulating the activating NK cell receptors. *Cancer Immunol Immunother*. 2010; 59:73-79. [PMID: 19526239].

Traverse JH, McKenna DH, Harvey K, Jorgenson BC, Olson RE, Bostrom N, Kadidlo D, Lesser JR, Jagadeesan V, Garberich R, and Henry TD. Results of a phase 1, randomized double-blind, placebo-controlled trial of bone marrow mononuclear stem cell administration in patients following ST-elevation in myocardial infarction. *Am Heart J*. 2010; 160(3):428-34. [PMID: 20826249].

Traverse JH, Henry TD, Vaughan DE, Ellis SG, Pepine CJ, Willerson JT, Zhao DX, Simpson LM, Penn MS, Byrne BJ, Perin EC, Gee AP, Hatzopoulos AK, McKenna DH, Forder JR, Taylor DA, Cogle CR, Baraniuk S, Olson RE, Jorgenson BC, Sayre SL, Vojvodic RW, Gordon DJ, Skarlatos SI, Moyé LA, and Simari RD. LateTIME: a phase-II, randomized, double-blinded, placebo-controlled, pilot trial evaluating the safety and effect of administration of bone marrow mononuclear cells 2 to 3 weeks after acute myocardial infarction. *Tex Heart Inst J*. 2010; 37:412-420. [PMID: 20844613].

Willerson JT, Perin EC, Ellis SG, Pepine CJ, Henry TD, Zhao DX, Lai D, Penn MS, Byrne BJ, Silva G, Gee A, Traverse JH, Hatzopoulos AK, Forder JR, Martin D, Kronenberg M, Taylor DA, Cogle CR, Baraniuk S, Westbrook L, Sayre SL, Vojvodic RW, Gordon DJ, Skarlatos SI, Moyé LA, and Simari RD. Intramyocardial injection of autologous bone marrow mononuclear cells for patients with chronic ischemic heart disease and left ventricular dysfunction (first mononuclear cells injected in the US [FOCUS]): rationale and design. *Am Heart J*. 2010 Aug; 160(2):215-23. doi: 10.1016/j.ahj.2010.03.029. [PMID: 20691824].



Zimmerlin L, Donnenberg VS, Pfeifer ME, Meyer EM, Peault B, Rubin JP, and Donnenberg AD. Stromal vascular progenitors in adult human adipose tissue. *Cytometry A*. 2010; 77:22-30. [PMID: 19852056].

## **2009**

Harting MT, Cox CS, Day MC, Walker P, Gee A, Brennenman MM, Grotta JC, and Savitz SI. Bone marrow-derived mononuclear cell populations in pediatric and adult patients. *Cytotherapy*. 2009; 11(4):480-4. doi: 10.1080/14653240902960452. [PMID: 19462318].

Phillips B, Giannoukakis N, and Trucco M. Dendritic cell-based therapy in type 1 diabetes mellitus. *Exp Rev Clin Immunol*. 2009; 5(3):325-39. [PMID: 20477010].

Traverse JH, Henry TD, Vaughan DE, Ellis SG, Pepine CJ, Willerson JT, Zhao DX, Piller LB, Penn MS, Byrne BJ, Perin EC, Gee AP, Hatzopoulos AK, McKenna DH, Forder JR, Taylor DA, Cogle CR, Olson RE, Jorgenson BC, Sayre SL, Vojvodic RW, Gordon DJ, Skarlatos SI, Moye LA, and Simari RD. Rationale and design for TIME: A phase II, randomized, double-blind, placebo-controlled pilot trial evaluating the safety and effect of timing of administration of bone marrow mononuclear cells after acute myocardial infarction. *Am Heart J*. 2009; 158:356-363. [PMID: 19699857].

Whiteside TL, Piazza P, Reiter A, Stanson J, Connolly NC, Rinaldo CR, Jr., and Riddler SA. Production of a dendritic cell-based vaccine containing inactivated autologous virus for therapy of patients with chronic human immunodeficiency virus type I infection. *Clin Vaccine Immunol*. 2009; 16(2):233-240. [PMID: 19038780].

## **2008**

Giannoukakis N, Phillips B, and Trucco M. Toward a cure for type 1 diabetes mellitus: diabetes-suppressive dendritic cells and beyond. *Pediatr Diabetes*. 2008; 9(3 Pt 2):4-13. [PMID: 18540865].

Harting MT, Baumgartner JE, Worth LL, Ewing-Cobbs L, Gee AP, Day MC, and Cox CS Jr. Cell therapies for traumatic brain injury. *Neurosurg Focus*. 2008; 24(3-4):E18. [PMID: 18341394].

Lee JJ, Foon KA, Mailliard RB, Muthuswamy R, and Kalinski P. Type 1-polarized dendritic cells loaded with autologous tumor are a potent immunogen against chronic lymphocytic leukemia. *J Leukoc Biol*. 2008; 84(1):319-25. [PMID: 18426971].

Pasquali L, Giannoukakis N, and Trucco M. Induction of immune tolerance to facilitate B-cell regeneration in type 1 diabetes. *Adv Drug Deliv Rev*. 2008; 60(2):106-13. [PMID: 18053613].

Phillips BE, Giannoukakis N, and Trucco M. Dendritic cell mediated therapy for immunoregulation of type 1 diabetes mellitus. *Pediatr Endocrinol Rev*. 2008;5(4):873-9. [PMID: 18552749].

Phillips B, Nylander K, Harnaha J, Machen J, Lakomy R, Styche A, Gillis K, Brown L, Gallo M, Knox J, Hogeland K, Trucco M, and Giannoukakis N. A microsphere-based vaccine prevents and reverses new-onset autoimmune diabetes. *Diabetes*. 2008; 57(6):1544-55. [PMID: 18316361].

## **2007**

Giannoukakis N, Rudert WA, and Trucco M. Dendritic cells for immunotherapy of type 1 diabetes. *Cell Science Reviews*. 2007; 3(3):250-78.

Kennedy-Nasser AA and Bollard CM. T cell therapies following hematopoietic stem cell transplantation: surely there must be a better way than DLI? *Bone Marrow Transplant*. 2007;40(2):93-104. [PMID: 17502898].



McKenna DH, Sumstad D, Bostrum N, Kadidlo DM, Fautsch S, McNearney S, DeWaard R, McGlave PB, Weisdorf DJ, Wagner JE, McCullough J, and Miller JS. Good manufacturing practices production of natural killer cells for immunotherapy: a six-year single institution experience. *Transfusion*. 2007; 47(3):520-8. [PMID: 17319835].

#### **2006**

Leen AM, Myers GD, Sili U, Huls MH, Weiss H, Leung KS, Carrum G, Krance RA, Chang CC, Molldrem JJ, Gee AP, Brenner MK, Heslop HE, Rooney CM, and Bollard CM. Monoculture-derived T lymphocytes specific for multiple viruses expand and produce clinically relevant effects in immunocompromised individuals. *Nat Med*. 2006; 12(10):1160-6. [PMID: 16998485].

Pasquali L, Fan Y, Trucco M, and Ringquist S. Rehabilitation of adaptive immunity and regeneration of beta-cells. *Trends Biotechnol*. 2006; 24(11):516-22. [PMID: 16963140].

#### **2005**

Leen AM, Myers GD, Bollard CM, Huls MH, Sili U, Gee AP, Heslop HE and Rooney CM. T cell immunotherapy for adenoviral infections of stem cell transplant recipients. *Ann N Y Acad Sci*. 2005;1062:104-15. [PMID: 16461793].

Miller JS, Soignier Y, Panoskaltsis-Mortari A, McNearney SA, Yun GH, Fautsch SK, McKenna D, Le C, Defor TE, Burns LJ, Orchard PJ, Blazar BR, Wagner JE, Slungaard A, Weisdorf DJ, Okazaki IJ, and McGlave PB. Successful adoptive transfer and in vivo expansion of human haploidentical NK cells in patients with cancer. *Blood*. 2005;105(8):3051-7. [PMID: 15632206].

#### **2004**

Godfrey WR, Ge YG, Spoden DJ, Levine BL, June CH, Blazar BR, and Porter SB. In vitro-expanded human CD4<sup>+</sup> CD25<sup>+</sup> T-regulatory cells can markedly inhibit allogeneic dendritic cell-stimulated MLR cultures. *Blood*. 2004;104(2):453-61. [PMID: 15031211].





## **Product-Related Bibliography**

---

### **Scientific Meeting Abstracts**

#### **2014**

Chen VC, Ye J, Hua G, Chen D, Lin Z, Liu J, Chai J, Shukla P, Wu J, Hsu D, and Couture LA. Development of a scalable suspension culture for cardiac differentiation from human pluripotent stem cells. Poster Session presented at: International Society for Stem Cell Research (ISSCR) 12th Annual Meeting; 2014 June 18-21; Vancouver, BC Canada. Poster W-3061.

Di Meo M, Stegner J, Tsytsykova A, Silberstein L, Jurkanas U, and Armant M. Cultivated autologous limbal epithelial cells for the treatment of limbal stem cell deficiency: product and process development. Ninth Annual HSCI Malkin Retreat. Cambridge, MA, May 23, 2014. Poster.

Chen, VC, Ye J, Hua G, Liu F, Chen D, Lin B, Chai J, Shukla P, Wu J, Hsu D and Couture LA. Development of a scalable suspension culture for cardiac differentiation from human pluripotent stem cells. Oral Abstract presented at: ASGCT (American Society of Gene & Cell Therapy) 17th Annual Meeting; 2014 May 21-24; Washington DC. Abstract 527.

#### **2013**

Schmuck E. Allogeneic "prime and boost" mesenchymal stem cell therapy for treatment of acute myocardial infarction in swine: a translational research study. October 15, 2013, Madison, WI.

Bloom D, Bhatia N, Hanley P, Gee A, Armant M, McKenna DH, Centanni JM, Lindblad R, Hei D, and Hematti P. A reproducible potency assay to measure differences in MSC-mediated T cell suppression. AABB Annual Meeting, October 2013. *Transfusion*. Volume 53, Issue Supplement S2, Sep 2013. Abstract/Poster #SP28.

Chen VC, Ye J, Giau H, Lin Z, Chen D, Huang P, Roy A, Huang P, Dang W; Chen W, Wu J, Hsu D, and Couture LA. Process Development for Scalable manufacturing of hESC-Derived Cardiomyocytes. Poster Session presented at: International Society for Stem Cell Research (ISSCR) 11th Annual Meeting; 2013 June 12-15; Boston, MA. Poster W-2334.

Schmuck E, Hacker T, Koch J, Hatt C, Tomkowiak M, Hendren N, Vigen K, Hematti P and Raval AN. "Prime and boost" allogeneic mesenchymal stem cell therapy is safe and effective for treatment of acute myocardial infarction in swine. Department of Medicine Research Day. Madison WI, June 7, 2013. \**Best poster presentation award*.

Chen VC, Ye J, Hua H, Lin Z, Chen D, Roy A, Chen W, Wu J, Hsu D, and Couture LA. Process Development for Scalable manufacturing of hESC-Derived Cardiomyocytes. Poster Session presented at: ASGCT (American Society of Gene & Cell Therapy) 16th Annual Meeting; 2013 May 15-18; Salt Lake City, UT. *Mol Ther*. Vol. 21, Supplement 1, May 2013. Abstract 474.

Vigen K, Schmuck EG, Hendren NS, Koch JM, Hacker TA, and Raval AN. Comparison of bSSFP-Cine Imaging and PV Loop Measurements in a Swine Model of Chronic Ischemic Cardiomyopathy. Proceedings of the 21st Annual Meeting of ISMRM, Salt Lake City, April, 22, 2013. Poster #1390.

Schmuck E, Hacker T, Koch J, Hatt C, Tomkowiak M, Hendren N, Schwahn D, Vigen K, Kim J, Hematti P and Raval AN. Allogeneic "prime and boost" mesenchymal stem cell therapy is safe and effective for treatment of acute myocardial infarction in swine. Wisconsin Stem Cell Symposium: Cell-Based Therapy for Heart and Vascular Disease: Pathways to Clinic. Madison WI, April 10, 2013. Poster.



## 2012

- Hendren N, Schmuck E, Hacker T, Koch J, and Raval A. Assessment of “prime and boost” mesenchymal stem cell therapy following myocardial infarction by pressure volume loops. *Cardiovascular Research Center Scientific Poster Fair*, Madison, WI, December 4, 2012.
- Gerdemann U, Katari UL, Keirnan J, Craddock JA, Salinas J, Liu H, Martinez C, Kennedy-Nasser A, Leung K, Gottschalk S, Gee AP, Krance RA, Brenner MK, Rooney CM, Heslop HE and Leen AM. Safety and clinical efficacy of rapidly-generated trivirus-directed T cells after allogeneic hematopoietic stem cell transplant. 2013 ASBMT Tandem Meeting, Salt Lake City, UT.
- Leen AM, Bollard CM, Mendizabal AM, Shpall EJ, Szabolcs P, Antin J, Kapoor N, Pai SY, Rowley S, Kebriaei P, Grilley B, Gee AP, Brenner MK, Rooney CM and Heslop HE. Multicenter study of “off-the-shelf” third party virus specific T-cells (VSTs) to treat adenovirus, cytomegalovirus (CMV) or Epstein Barr Virus (EBV) infection after hemopoietic stem cell transplantation (HSCT). 2012 ASH Annual Meeting, Atlanta, GA. Abstract 721.
- Gerdemann U, Katari UL, Keirnan J, Craddock JA, Salinas J, Liu H, Martinez C, Kennedy-Nasser A, Leung K, Gottschalk S, Gee AP, Krance RA, Brenner MK, Rooney CM, Heslop HE and Leen AM. Safety and clinical efficacy of rapidly-generated trivirus-directed T cells after allogeneic hematopoietic stem cell transplant. 2012 ASH Annual Meeting, Atlanta, GA. Abstract 223.
- Brunstein CG, Blazar BR, Miller JS, Cao Q, Hippen K, McKenna DH, and Wagner JE. Impact of umbilical cord blood (UCB) T regulatory cells (Tregs) on infection risk early after UCB transplant. 2012 ASH Annual Meeting, Atlanta, GA. Abstract 4188.
- Hanley PJ, Mei Z, Yang B, Mir O, Parsha K, Durett A, Rice RB, Cabreira-Hansen MG, Savitz SI, Gee AP. Clinical-scale expansion of human bone marrow-derived mesenchymal stromal cells to treat patients after ischemic stroke. 2012 ASH Annual Meeting, Atlanta, GA. Abstract 3021.
- Hanley PJ, Mei Z, Yang B, Mir O, Parsha K, Durett A, Rice RB, Cabreira-Hansen MG, Savitz SI, Gee AP. Clinical-Scale Expansion of Human Bone Marrow-Derived Mesenchymal Stromal Cells to Treat Patients After Ischemic Stroke. 2012 ASH Annual Meeting, Atlanta, GA. Poster.
- Szmania S, Garg TK, Lapteva N, Lingo JD, Greenway AD, Stone K, Woods E, Khan J, Stivers J, Nair B, Baxter-Lowe LA, Bost A, Campana D, Epstein J, Gee AP, Brenner MK, Usmani SZ, Waheed S, Rooney CM, Cottler-Fox M, Barlogie B, and van Rhee F. Fresh ex vivo expanded natural killer cells demonstrate robust proliferation in vivo in high-risk relapse multiple myeloma (MM) patients. *Blood*. 2012. ASH Annual Meeting, Atlanta, GA. Abstract 579.
- Szmania S, Lapteva N, Garg T, Lingo J, Greenway A, Bost A, Stone K, Khan J, Woods E, Nair B, Campana D, Epstein J, Brenner M, Gee A, Cottler-Fox M, Barlogie B, Rooney C, and van Rhee F. Expanded natural killer (NK) cells for immunotherapy: fresh and made to order. *Blood* (ASH Annual Meeting Abstracts). 2012;120:1912.
- Tolar J, Curtsinger J, McElmurry R, McCullar V, Verneris MR, van Rhee F, Lapteva N, Rooney CM, Wagner JE, Blazar BR, and Miller JS. Optimal xenogeneic adoptive transfer of human NK cells: fresh NK cells and IL-15 administration are superior to frozen NK cells and IL-2. *Blood*. 2012. ASH Annual Meeting, Atlanta, GA. Abstract 346.



Gerdemann U, Katari UL, Keirnan JM, Craddock JA, Dean TL, Liu H, Martinez CA, Kennedy-Nasser AA, Leung KS, Gottschalk S, Gee AP, Krance RA, Brenner MK, Rooney CM, Heslop HE and Leen AM. Adoptive transfer of rapidly-generated multivirus-specific T cells to treat adenovirus, EBV and CMV infections of hematopoietic stem cell transplant recipients. 2012 BMT Tandem Meetings, San Diego, CA. Abstract 45.

Brunstein CG, McKenna DH, DeFor TE, Sumstad D, Ratajczak M, Laughlin MJ, and Wagner JE. Priming of hematopoietic progenitor cells (HPC) with complement fragment 3a (c3a) to promote homing of umbilical cord blood (UCB): safety profile. 2012 BMT Tandem Meetings, San Diego, CA. Abstract 20.

### **2011**

Bloom D, Elmer C, Drier D, Sheerar D, Schell K, Centanni J, Hei D, and Hematti P. Characterization of bone marrow-derived mesenchymal stromal cells grown in different culture media. AABB Annual Meeting, October 2011. *Transfusion*. Volume 51, Issue Supplement S3, Sep 2011. Abstract/Poster #SP505.

Leen AM, Bollard CM, Mendizabal A, Shpall EJ, Szabolcs P, Antin J, Kapoor N, Heaton C, Grilley B, Gee AP, Brenner MK, Rooney CM and Heslop HE. Most closely HLA-matched allogeneic virus specific cytotoxic tlymphocytes (CTL) to treat persistent reactivation or infection with adenovirus, CMV and EBV after hemopoietic stem cell transplantation (HSCT). *Biol Blood Marrow Transplant*. 2011. Vol. 17, Issue 2, Supplement, Pages S151-S152.

### **2010**

Leen AM, Bollard CM, Mendizabal A, Shpall EJ, Szabolcs P, Antin J, Kapoor N, Heaton C, Grilley B, Gee AP, Brenner MK, Rooney CM and Heslop HE. Most closely HLA-matched allogeneic virus specific cytotoxic T-lymphocytes (CTL) to treat persistent reactivation or infection with adenovirus, CMV and EBV after hemopoietic stem cell transplantation (HSCT). 2010 ASH Annual Meeting, San Diego, CA. Abstract 829.

### **2008**

Cooley S, Gada P, McKenna D, McKenna D, McCullar V, Fautsch S, Verneris m, Blazar BR, Burns LJ, McGlave PB, Weisdorf DJ, and Miller JS. Successful haploidentical hematopoietic cell engraftment using a non-myeloablative preparative regimen including natural killer (NK) cells. 2008 ASH Annual Meeting, San Francisco, CA. *Blood*. 2008; 112: Abstract 827.

Griffin DL, Pfiefer ME, Zimmerlin L, Rubin JP, and Donnenberg AD. Translational scale-up: bridging the gap between research and clinical processing of pre-adipocytes. June 2008 ISSCR Annual Meeting, Philadelphia, PA. ISSCR 2008: Abstract No. 263, p29.

### **2007**

Bollard CM, Myers GD, Weiss H, Gee AP, Leung K, Krance RA, Brenner MK, Rooney CM, Heslop HE, and Leen AM. Cytotoxic T lymphocyte therapy for the treatment and prevention of adenovirus infection after stem cell transplant. February 2007 ASBMT Meeting, Keystone, CO. *Biol Blood Marrow Transplant*. Best abstract award. 2007;13(2), page 1.

### **2006**

Bollard CM, Myers GD, Leen A, Huls H, Buza E, Chang J, Leung K, Carrum G, Krance RA, Molldrem J, Brener MK, Rooney CM, and Heslop HE. The clinical use of donor-derived virus- specific cytotoxic T lymphocytes reactive against cytomegalovirus (CMV), adenovirus and Epstein Barr virus (EBV). February 2006 ASBMT Meeting, Honolulu, HI. *Biol Blood Marrow Transplant*. 2006;12(2):S2;220, page 77.



- Kadidlo D, Bostrom N, Adams S, Fautsch S, McCullough J, Wagner JE, Miller JS, and McKenna DH. Validation of natural killer cell activation during long-distance shipping. October 2006 American Association of Blood Banks Annual Meeting, Miami Beach, FL. *Transfusion*. 2006;46:SP67, pgs. 59A-60A.
- McKenna D, Sumstad D, Bostrom N, Kadidlo DM, Fautsch S, McNearney S, Dewaard R, wagner JE, McCullough J, and Miller JS. Clinical-scale production of natural killer cells for immunotherapy: a six year single institutional experience. October 2006 American Association of Blood Banks Annual Meeting, Miami Beach, FL. *Transfusion*. 2006;46:S96-040G, page35A.
- Miller JS, Brunstein CG, Cooley S, Verneris MR, Panoskaltsis-Mortari A, Burns LJ, MdKenna D, Dusenbery K, Stevens C, Rubenstein P, Tomblyn M, Arora M, MacMillan ML, DeFor T, Le C, McGlave PB, Blazar BR, and Weisdort DJ. A novel triple umbilical cord blood transplant (UCBT) strategy to promote NK cell immunotherapy (Unit1) with a fully ablative preparative regimen followed by a double UCBT in patients with refractory AML. December 2006 American Society of Hematology 48th Annual Meeting, Orlando, FL, *Blood*. 2006;108 No.11;340-III.
- Whiteside TL, Piazza P, Connolly N, Connolly N, Riddler S, and Rinaldo C. Autologous dendritic cell (DC)-based HIV-1 vaccine: endogenous virus-superinfected apoptotic T cells fed to DC. May 2006 Annual Meeting and Scientific Conference of the International Society for Cellular Therapy, Berlin, Germany. *Cytotherapy*. 2006; 8:S1. Abstract 139. 1465-3249.

## **2005**

- Bollard CM, Leen A, Huls H, Myers GD, Sili U, Rooney CM, and Heslop HE. The generation of donor-derived virus-specific cytotoxic T lymphocytes reactive against cytomegalovirus and adenovirus antigens for clinical use. February 2005 ASBMT Meeting, Keystone, CO. *Biol Blood Marrow Transplant*. 2005;11(2);42, page 15.Oral presentation.
- Myers GD, Leen AM, Sili U, Huls MH, Buza E, Leung K, Carrum G, Krance RA, Brenner MK, Rooney CM, Heslop HE, and Bollard CM. The clinical use of donor-derived virus-specific cytotoxic T lymphocytes reactive against cytomegalovirus (CMV), adenovirus and Epstein Barr virus (EBV). 2005 ASH Annual Meeting. *Blood*. 2005;106(11);81.
- Myers GD, Leen A, Huls H, Buza E, Chang J, Krance RA, Carrum G, Brenner MK, Rooney CM, Heslop HE, and Bollard CM. The use of genetically modified antigen presenting cells to generate donor-derived virus-specific cytotoxic T lymphocytes reactive against CMV and adenoviral antigens for clinical use. 2005 ASGT Annual Meeting, St. Louis, MO. *Mol Ther*. 2005;11;1074, page S414.

## **2004**

- Miller JS, Soignier Y, Panoskaltsis-Mortari A, McKenna D, Le C, Defor TE, Burns LJ, Orchard PJ, Blazar BR, Wagner JE, Slungaard A, Weisdorf DJ, Okazaki IJ, and McGlave PB. Successful remission of poor prognosis AML after adoptive transfer and in vivo of human haploidentical NK cells. November 2004 American Society of Hematology, 46th Annual Meeting, San Diego, CA. *Blood*. 2004;104 No.11:260. Oral presentation.