

## William Earl Janssen, Ph.D.

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### 1. Education and Training (list all degrees awarded and training programs completed)

B.A. in Biophysics ( <i>Honors &amp; Distinction</i> ), University of California, Berkeley, California	1977
M.S. in Microbiology, University of Colorado Health Sciences Center, Denver, Colorado	1979
Ph.D. in Biophysical Sciences, State University of New York, Buffalo, New York	1984
Post-Doctoral Fellowship, University of Pennsylvania, Philadelphia, Pennsylvania	1984
Post-Doctoral Fellowship, University of Florida, Gainesville, Florida	1985-88

### 2. Key Accomplishments Summary

My focus over the course of my career has been on applying the sciences of cell biology, experimental hematology and immunology, along with my educational foundation in biophysics and bioengineering, to the development and application of cellular products that have therapeutic potential. Beginning from a focus in the field of blood and marrow transplantation wherein I was involved with early studies of purging of autologous marrow products with the goal of rendering them free of neoplastic cells, I expanded my area of expertise to include isolation, culturing, and genetic manipulation of autologous tumor cells and dendritic cells for use as anti-cancer vaccines. More recently, I became involved in adoptive cell transfer, overseeing production of expanded tumor infiltrating lymphocyte (TIL) products and expanding Tregs in co-culture with recipient dendritic cells for use as a biologic graft versus host or host versus graft prophylaxis. I have also directed production of gene modified immune cells (CAR-T) and hematopoietic progenitors for correction of genetic immunologic defects (X-linked SCID). Along the way, I have also become involved in the organizations promoting safe translation of cellular therapies, namely the International Society for Cell and Gene Therapy (ISCT), and the Foundation for Accreditation of Cellular Therapy (FACT). I was among the founders of both organizations and have served in multiple leadership roles in both organizations as well. I have also developed a skill set with respect to writing and advancing IND and IDE applications through the FDA approval process. The most rewarding of my efforts has been mentoring, and in the course of the above activities, I have mentored several individuals who now, themselves, hold leadership roles in both academic and industry settings.

### 3. Professional Career

Associate Research Scientist Department of Pediatrics University of Florida Gainesville, Florida	1988-89
Assistant Professor Department of Medicine (joint appointment Department of Pathology) University of South Florida Tampa, Florida	1989-1994
Director, Stem Cell Processing Laboratory H. Lee Moffitt Cancer Center, Blood and Marrow Transplant Program Tampa, Florida	1989-2002
Associate Professor Department of Medicine (joint appointment Department of Pathology)	1994-1998

University of South Florida  
Tampa, Florida

Associate Professor  
Department of Interdisciplinary Oncology  
University of South Florida  
Tampa, Florida

1998-2007

Director, Cell Therapies Facility  
H. Lee Moffitt Cancer Center, Blood and Marrow Transplant Program  
Tampa, Florida

2002-2007

Associate Member, Department of Blood and Marrow Transplant,  
Moffitt Cancer Center  
Associate Professor, Department of Oncologic Sciences  
University of South Florida  
Tampa, Florida

2008-2010

Director, Cell Therapies Facility and Cell Therapies Core  
Moffitt Cancer Center, Programs in Blood and Marrow Transplant  
and Immunotherapy  
Tampa, Florida

2007-2014

Senior Member, Department of Blood and Marrow Transplant,  
Moffitt Cancer Center  
Professor, Department of Oncologic Sciences  
University of South Florida  
Tampa, Florida

2010-2014

Member, Department of Bone Marrow Transplantation and  
Cellular Therapy and Director, Human Applications Lab  
St. Jude Children's Research Hospital  
Memphis, Tennessee

2014-2019

Principal  
WEJ Cell and Gene Therapy Consulting Services, LLC  
Eads, Tennessee

2020-present

#### **4. Certifications and Licensure** *[List in chronological order with oldest entries first]*

State Medical Technologist License, Florida (inactive)

1989-2016

#### **5. Professional Memberships**

International Society for Cell and Gene Therapy (ISCT)  
American Society for Blood and Marrow Transplant  
Society for Immunotherapy of Cancer

1992-present

1992-present

2003-present

## 6. Honors and Awards

Leukemia Society of America, Post-doctoral Fellowship

1986-1989

## 7. Institutional and Committee Assignments

GMP Oversight Committee

2015-present

## 8. Professional Administrative Services

Foundation for Accreditation of Cellular Therapy

Volunteer Inspector

1997-2015

Accreditation Committee (Member by Appointment)

2009-2012

Process Standards Committee, Chair

2010-2012

Board of Directors (Member by Appointment)

2010-2013

ICCBBA (formerly International Council for Commonality in Blood Banking Automation, Parent organization for ISBT128 cell and tissue coding and labeling standard)

Member, Cell Therapies Coding and Labeling Advisory Group

2012-present

International Society for Cellular Therapy,

North American Legal and Regulatory Affairs Committee, member

2003-2010

Chair, North American Legal and Regulatory Affairs Committee

2011-2014

Elected Member, Board of Advisors

2004-2006 and 2008-2010

Annual Meeting 2015, Organizing Committee

2014-2015

North American Regional Vice President

2015-2016

North American Regional Meeting, 2016, Co-chair

2015-2016

Ad Hoc Reviewer, Experimental Hematology, Blood, Transfusion,

Journal of Hematotherapy and Stem Cell Research,

Cytotherapy, Bone Marrow Transplantation,

Biology of Blood and Marrow Transplantation

1995-present

## 9. Formal Education/Teaching Activities

**Course Instructor:** General Pathology (Medical School), Hematology Section, Department of Pathology, College of Medicine, University of South Florida, Tampa, FL

1993-2005

**Course Instructor:** Topics in Biomedical Engineering (Cell separation methods for biomedical engineering). Department of Chemical Engineering, College of Engineering. University of South Florida. Tampa, FL.

1999-2002

**Course Instructor:** Cancer Research Techniques (GMS-6056). Department of Oncologic Science, University of South Florida, Tampa, FL.

2002-2013

**Course Instructor:** Cancer Immunology. Department of Oncologic Sciences. University of South Florida, Tampa, Florida.

2012-2014

**Lecturer:** Emerging Technologies in Biomedical Engineering. Department of Chemical Engineering, University of South Florida, Tampa, Florida.

2012-2014

## 10. Grant Awards:

### A. Completed Grants:

**PI = William Dalton, W. Janssen – Co-investigator**

Account #: 3P30CA076292

Dates: 2012-2014 (left grant on departure from institution)

Source: NCI

Title: Moffitt Cancer Center Support Grant

% Effort: 5%

Role in Study: Director of Cell Therapies Facility shared resource

**PI = Claudio Anasetti, W. Janssen – Co-investigator**

Account # 1 R01 HL114994-01A1

Dates: 2013-2014 (left grant on departure from institution)

Source: NCI

Title: Adoptive Transfer Of Donor Tregs Specific Against Host Alloantigens

% Effort: 10%

Role in Study: Director of Cell Therapies Facility (processing and prep of Tregs);  
Responsible for required IND and IDE.

**PI = William Janssen**

Account # n/a

Dates: 2011-2014 (left grant on departure from institution)

Source: V-Foundation

Title: Combined Cell Therapies for Treatment of Advanced Neuroblastoma.

% Effort: 15%

Role in study: PI

**11. Clinical Trials Involvement** (Notes: Moffitt Cancer Center clinical trials are limited to those open to accrual in my last two years of appointment at that institution. Dates shown are for protocol activation).

1. Use of GM-CSF secreting CD40L expressing cell line as vaccine for MDS (HLM14998). Moffitt Cancer Center, Jul 2007. **Co-investigator.**
2. Use of p53 gene transduced dendritic cells as vaccine for small cell lung cancer (HLM15206). Moffitt Cancer Center. Jul 2007. **Co-investigator**
3. Use of peptide and KLH pulsed dendritic cells as vaccine for melanoma (HLM15280). Moffitt Cancer Center. Sep 2007. **Co-investigator**
4. Tumor infiltrating lymphocytes (TIL) expanded and infused for treatment of melanoma (HLM15781). Moffitt Cancer Center. Apr 2011. **Co-investigator.**
5. Use of p53 gene transduced dendritic cells as vaccine for breast cancer (HLM16025). Moffitt Cancer Center. Sep 2011. **Co-investigator.**
6. Use of GM-CSF secreting, CD40L expressing cell line, in combination with lung adenocarcinoma cell lines transfected with CCL-21 gene for treatment of non-small cell lung cancer (HLM16439) Moffitt Cancer Center. Sep 2011. **Co-investigator.**
7. Use of intra-tumor administered dendritic cells in soft tissue sarcoma (HLM16441) Moffitt Cancer Center. Jan 2012. **Co-investigator.**
8. Haploidentical Donor Hematopoietic Progenitor Cell And Natural Killer Cell Transplantation With A TLI Based Conditioning Regimen In Patients With Hematologic Malignancies (HAPNK1). SJCRH, Apr. 2013. **Co-investigator.**
9. Neuroblastoma Protocol 2012: Therapy For Children With Advanced Stage High-Risk Neuroblastoma (NB2012). SJCRH. Jan 2014. **Co-Investigator.**
10. Retrospective Study Using Production Records To Identify Sources Of Variability In Cellular Therapy Products (XPD15-082). SJCRH. May 2015. **PI.**

11. Provision Of TCR $\gamma\delta$  T Cells And Memory T Cells Plus Selected Use Of Blinatumomab In Naïve T Cell Depleted Haploidentical Donor Hematopoietic Cell Transplantation For Patients With Hematologic Malignancy Relapsed Or Refractory Despite Prior Transplantation (REF2HCT). SJCRH. Jun 2016. **Co-Investigator.**
12. Multicenter Expanded Access Protocol of ATA129 for Subjects with Epstein-Barr Virus-Associated Viremia or Malignancies for Whom there are No Appropriate Alternative Therapies (EBV201). SJCRH. Apr 2017. **Co-Investigator.**
13. Multicenter, Open-Label, Phase 3 Trial of ATA129 for Allogeneic Hematopoietic Cell Transplant Subjects with Epstein-Barr Virus-Associated Post-Transplant Lymphoproliferative Disease after Failure of Rituximab (MATCH Study) (EBV301). SJCRH Oct 2017. **Co-investigator.**
14. Haplocompatible Transplant Using TCR $\alpha$ /B Depletion Followed By Cd45ra-Depleted Donor Lymphocyte Infusions For Severe Combined Immunodeficiency (SCID) (SCIDBMT). SJCRH Jun 2018. **Co-Investigator.**
15. SJCAR19: A Phase I/II Study Evaluating SJCAR19 (CD19-Specific CAR Engineered Autologous T-Cells) In Pediatric And Young Adult Patients  $\leq$  21 Years Of Age With Relapsed Or Refractory Cd19<sup>+</sup> Acute Lymphoblastic Leukemia (SJCAR19) SJCRH Jun 2018. **Co-Investigator.**

## 12. Publication Record:

### A. Peer Reviewed Publications:

#### i. Original Research Articles:

1. **Janssen WE**, Snell FM, Anbar M. Rate of non-adherent cell loss from long-term cultures of murine bone marrow: effect of medium conditioned by the adherent cell population. *Cell and Tissue Kinetics* 18:613-621, 1985. **First author.**
2. **Janssen WE**, Munger KL, Gee AP. The migration of hematopoietic cells: an in vitro study system. *Leukemia* 2:307-312, 1988. **First author.**
3. **Janssen WE**, Lee C, Gross S, Gee AP. Low antigen density leukemia cells: selection and comparative resistance to antibody-mediated marrow purging. *Exp Hematol* 17:252-257, 1989. **First author.**
4. **Janssen WE**, Rios AM. Non-specific cell binding characteristics of para-magnetic polystyrene microspheres used for antibody-mediated cell selection. *J Immunol Meth* 121:289-294, 1989. **First author.**
5. Graham-Pole JR, Gee A, **Janssen W**, Lee C, Gross S. Immunomagnetic purging of bone marrow: a model for negative cell selection. *Am J Pediatr Hematol Oncol* 12:257-261, 1990. **Co-author.**
6. **Janssen WE**, Johnson KS, Lee C, Cassano W. Relative efficiency of leukemic cell depletion using anti-murine-IgG1(Fc) or anti-murine-IgG coated immunomagnetic microbeads. *Bone Marrow Transplant* 5:19-22, 1990. **First author.**
7. Graham-Pole J, Gee A, Emerson S, Gallo J, Lee C, Luzins J, **Janssen WE**, Pick T, Worthington-White D, Elfenbein G, et al. Myeloablative chemoradiotherapy and autologous bone marrow infusions for treatment of neuroblastoma: factors influencing engraftment. *Blood* 78:1607-1614, 1991. **Co-author.**
8. Graham-Pole JG, Casper J, Elfenbein G, Gee A, Gross S, **Janssen W**, Koch P, Marcus R, Pick T, Shuster J, et al. High-dose chemoradiotherapy supported by marrow infusions for

- advanced neuroblastoma: a Pediatric Oncology Group study. J Clin Oncol 9:152-158, 1991. **Co-author.**
9. Fields KK, Elfenbein GJ, Saleh RA, Zorsky PE, **Janssen WE**, Perkins JB, Saleh TG, Piazza JT, Kronish LE, Machak MC, et al. Ifosfamide, carboplatin, and etoposide in combination for induction and high-dose chemotherapy: focus on breast cancer and lymphoma. Hematol Oncol 10:61-74, 1992. **Co-author.**
  10. **Janssen WE**. The CD34+ fraction in blood and marrow is not universally predictive of CFU-GM. Exp Hematol 20, 1992. **First author.**
  11. **Janssen WE**, Farmelo MJ, Lee C, Smilee R, Kronish L, Elfenbein GJ. The CD34+ cell fraction in bone marrow and blood is not universally predictive of CFU-GM. Exp Hematol 20:528-530, 1992. **First author.**
  12. **Janssen WE**, Lee C, Smilee R, Carter R. Use of the Terumo SteriCell for the processing of bone marrow and peripheral blood stem cells. J Hematother 1:349-359, 1992. **Co-author.**
  13. Fields KK, Elfenbein GJ, Perkins JB, Hiemenz JW, **Janssen WE**, Zorsky PE, Ballester OF, Kronish LE, Foody MC. Two novel high-dose treatment regimens for metastatic breast cancer- ifosfamide, carboplatin, plus etoposide and mitoxantrone plus thiotepa: outcomes and toxicities. Semin Oncol 20:59-66, 1993. **Co-author.**
  14. Fields KK, Perkins JP, Hiemenz JW, Zorsky PE, **Janssen WE**, Kronish LE, Machak MC, Elfenbein GJ. Intensive dose ifosfamide, carboplatin, and etoposide followed by autologous stem cell rescue: results of a phase I/II study in breast cancer patients. Surg Oncol 2:87-95, 1993. **Co-author.**
  15. **Janssen WE**. Peripheral blood and bone marrow hematopoietic stem cells: are they the same? Semin Oncol 20:19-27, 1993. **First author.**
  16. **Janssen WE**, Hiemenz JW, Elfenbein GJ. When, how, what, and where to purge are not the questions either. J Hematother 2:3-5, 1993. **Co-author.**
  17. Bosek V, **Janssen WE**, Burdash N, Nolan J, Patel M. General anesthesia and bone marrow harvesting procedure have no effect on the concentration of CD34 stem cells in peripheral venous blood. Bone Marrow Transplant 13:498, 1994. **Co-first author.**
  18. Fields KK, Agalotis DP, **Janssen WE**, Perkins JB, Ballester OF, Hiemenz JW, Zorsky PE, Elfenbein GJ. High-dose chemotherapy and the treatment of metastatic breast cancer: Selecting the regimen and the source of stem cells. Cancer Control 1:213-218, 1994. **Co-author.**
  19. Fields KK, Elfenbein GJ, Perkins JB, **Janssen WE**, Ballester OF, Hiemenz JW, Zorsky PE, Kronish LE, Foody MC. High-dose ifosfamide/carboplatin/etoposide: maximum tolerable doses, toxicities, and hematopoietic recovery after autologous stem cell reinfusion. Semin Oncol 21:86-92, 1994. **Co-author.**
  20. **Janssen WE**, Hiemenz JW, Fields KK, Zorsky PE, Ballester OF, Goldstein SC, Elfenbein GJ. Blood and bone marrow hematopoietic stem cells for transplantation: A comparative review. Cancer Control 1:225-230, 1994. **First author.**
  21. Fields KK, Elfenbein GJ, Lazarus HM, Cooper BW, Perkins JB, Creger RJ, Ballester OF, Hiemenz JH, **Janssen WE**, Zorsky PE. Maximum-tolerated doses of ifosfamide, carboplatin, and etoposide given over 6 days followed by autologous stem-cell rescue: toxicity profile. J Clin Oncol 13:323-332, 1995. **Co-author.**
  22. **Janssen WE**, Smilee RC, Elfenbein GJ. A prospective randomized trial comparing blood- and marrow-derived stem cells for hematopoietic replacement following high-dose chemotherapy. J Hematother 4:139-140, 1995. **First author.**
  23. Ballester OF, Agalotis DP, Hiemenz JW, **Janssen WE**, Fields KK, Zorsky PE, Goldstein SC, Perkins JB, Elfenbein GJ. Phase I-II study of high-dose busulfan and cyclophosphamide

- followed by autologous peripheral blood stem cell transplantation for hematological malignancies: toxicities and hematopoietic recovery. *Bone Marrow Transplant* 18:9-14, 1996. **Co-author.**
24. Fields KK, Elfenbein GJ, Trudeau WL, Perkins JB, **Janssen WE**, Moscinski LC. Clinical significance of bone marrow metastases as detected using the polymerase chain reaction in patients with breast cancer undergoing high-dose chemotherapy and autologous bone marrow transplantation. *J Clin Oncol* 14:1868-1876, 1996. **Co-senior author.**
  25. Ballester OF, Tummala R, **Janssen WE**, Fields KK, Hiemenz JW, Goldstein SC, Perkins JB, Sullivan DM, Rosen R, Sackstein R, Zorsky P, Saez R, Elfenbein GJ. High-dose chemotherapy and autologous peripheral blood stem cell transplantation in patients with multiple myeloma and renal insufficiency. *Bone Marrow Transplant* 20:653-656, 1997. **Co-author.**
  26. Bashey A, Corringham S, Gilpin E, Fields KK, Smilee RC, DeFrancisco C, Santos-Ada O, Holman P, Carrier E, Ho AD, Lane TA, Ball ED, **Janssen WE**, Law P. Simultaneous administration of G-CSF and GM-CSF for re-mobilization in patients with inadequate initial progenitor cell collections for autologous transplantation. *Cytotherapy* 2:195-200, 2000. **Co-senior author.**
  27. Sanchez-Ramos J, Song S, Cardozo-Pelaez F, Hazzi C, Stedeford T, Willing A, Freeman TB, Saporta S, **Janssen W**, Patel N, Cooper DR, Sanberg PR. Adult bone marrow stromal cells differentiate into neural cells in vitro. *Exp Neurol* 164:247-256, 2000. **Co-author.**
  28. Antonia SJ, Seigne J, Diaz J, Muro-Cacho C, Extermann M, Farmelo MJ, Friberg M, Alsarraj M, Mahany JJ, Pow-Sang J, Cantor A, **Janssen W**. Phase I trial of a B7-1 (CD80) gene modified autologous tumor cell vaccine in combination with systemic interleukin-2 in patients with metastatic renal cell carcinoma. *J Urol* 167:1995, 2002. **Co-author.**
  29. Fallon P, Gentry T, Balber AE, Boulware D, **Janssen WE**, Smilee R, Storms RW, Smith C. Mobilized peripheral blood SSCloALDHbr cells have the phenotypic and functional properties of primitive haematopoietic cells and their number correlates with engraftment following autologous transplantation. *Br J Haematol* 122:99-108, 2003. **Co-author.**
  30. Antonia SJ, Mirza N, Fricke I, Chiappori A, Thompson P, Williams N, Bepler G, Simon G, **Janssen W**, Lee JH, Menander K, Chada S, Gabrilovich DI. Combination of p53 cancer vaccine with chemotherapy in patients with extensive stage small cell lung cancer. *Clin Cancer Res* 12:878-887, 2006. **Co-author.**
  31. Dessureault S, Noyes D, Lee D, Dunn M, **Janssen W**, Cantor A, Sotomayor E, Messina J, Antonia SJ. A phase-I trial using a universal GM-CSF-producing and CD40L-expressing bystander cell line (GM.CD40L) in the formulation of autologous tumor cell-based vaccines for cancer patients with stage IV disease. *Ann Surg Oncol* 14:869-884, 2007. **Co-author.**
  32. Fishman M, Hunter TB, Soliman H, Thompson P, Dunn M, Smilee R, Farmelo MJ, Noyes DR, Mahany JJ, Lee JH, Cantor A, Messina J, Seigne J, Pow-Sang J, **Janssen W**, Antonia SJ. Phase II trial of B7-1 (CD-86) transduced, cultured autologous tumor cell vaccine plus subcutaneous interleukin-2 for treatment of stage IV renal cell carcinoma. *J Immunother* 31:72-80, 2008. **Co-senior author.**
  33. Chiappori AA, Soliman H, **Janssen WE**, Antonia SJ, Gabrilovich DI. INGN-225: a dendritic cell-based p53 vaccine (Ad.p53-DC) in small cell lung cancer: observed association between immune response and enhanced chemotherapy effect. *Expert Opin Biol Ther* 10:983-991, 2010. **Co-author.**
  34. Field T, Perkins J, Huang Y, Kharfan-Dabaja MA, Alsina M, Ayala E, Fernandez HF, **Janssen W**, Lancet J, Perez L, Sullivan D, List A, Anasetti C. 5-Azacitidine for myelodysplasia before allogeneic hematopoietic cell transplantation. *Bone Marrow Transplant* 45:255-260, 2010. **Co-author.**

35. Gunter KC, Caplan AL, Mason C, Salzman R, **Janssen WE**, Nichols K, Bouzas LF, Lanza F, Levine BL, Rasko JE, Shimosaka A, Horwitz E. Cell therapy medical tourism: time for action. *Cytotherapy* 12(8):965-968, 2010. **Co-author.**
36. **Janssen WE**, Ribickas A, Meyer LV, Smilee RC. Large-scale Ficoll gradient separations using a commercially available, effectively closed, system. *Cytotherapy* 12:418-424, 2010. **First author, Senior author.**
37. Perkins J, Field T, Kim J, Kharfan-Dabaja MA, Fernandez H, Ayala E, Perez L, Xu M, Alsina M, Ochoa L, Sullivan D, **Janssen W**, Anasetti C. A randomized phase II trial comparing tacrolimus and mycophenolate mofetil to tacrolimus and methotrexate for acute graft-versus-host disease prophylaxis. *Biol Blood Marrow Transplant* 16:937-947, 2010. **Co-senior author.**
38. Kharfan-Dabaja MA, Chavez JC, Yu D, Zhu W, Fernandez-Vertiz EI, Perkins J, Shapiro J, Bookout R, Perez L, Fernandez, HF, Komrokji, RS, Lancet, J, Brand, L, Field, T, Ayala, E, **Janssen, W**, List, AF, Anasetti, C. Severe hypoalbuminemia at day 90 predicts worse nonrelapse mortality and overall survival after allogeneic hematopoietic stem cell transplantation for acute myelogenous leukemia and myelodysplastic syndrome. *Biol Blood Marrow Transplant* 17(3):384-393, 2011. **Co-author.**
39. Finkelstein SE, Iclozan C, Bui MM, Cotter MJ, Ramakrishnan R, Ahmed J, Noyes, DR, Cheong, D, Gonzalez, RJ, Heysek, RV, Berman, C, Lenox, BC, **Janssen, W**, Zager, JS, Sondak, VK, Letson, GD, Antonia, SJ, Gabrilovich, DI. Combination of external beam radiotherapy (EBRT) with intratumoral injection of dendritic cells as neo-adjuvant treatment of high-risk soft tissue sarcoma patients. *Int J Radiat Oncol Biol Phys* 82(2):924-932, 2012. **Co-author.**
40. **Janssen WE**, Rahn, D, Hackett, M, Coyle, D, Tomblyn, M, Smilee, RC, Anasetti, C, Fernandez, HF. Apheresis and transplant of hematopoietic progenitor cells from donors aged sixty and above. *Bone Marrow Transplant* 47(12):1520-1525, 2012. **First author, Senior author.**
41. Finkelstein SE, Rodriguez F, Dunn M, Farmello MJ, Smilee R, **Janssen W**, Kang L, Chuang T, Seigne J, Pow-Sang J, Torres-Roca JF, Heysek R, Biagoli M, Shankar R, Scott J, Antonia S, Gabrilovich D, Fishman M. Serial assessment of lymphocytes and apoptosis in the prostate during coordinated intraprostatic dendritic cell injection and radiotherapy. *Immunotherapy* 4(4):373-382, 2012. **Co-author.**
42. Perkins JB, Shapiro JF, Bookout RN, Yee GC, Anasetti C, **Janssen WE**, Fernandez HF. Retrospective comparison of filgrastim plus plerixafor to other regimens for remobilization after primary mobilization failure: Clinical and economic outcomes. *Am J Hematol* 87(7):673-677, 2012. **Co-senior author.**
43. Pidala J, Kim J, Jim H, Kharfan-Dabaja MA, Nishihori T, Fernandez HF, Tomblyn M, Perez L, Perkins J, Xu M, **Janssen WE**, Veerapathran A, Betts BC, Locke FL, Ayala E, Field T, Ochoa L, Alsina M, Anasetti C. A randomized phase II study to evaluate tacrolimus in combination with sirolimus or methotrexate after allogeneic hematopoietic cell transplantation. *Haematologica* 97(12):1882-1889, 2012. **Co-author.**
44. Pilon-Thomas S, Kuhn L, Ellwanger S, **Janssen W**, Royster E, Marzban S, Kudchadkar R, Zager J, Gibney G, Sondak VK, Weber J, Mule JJ, Sarnaik AA. Efficacy of adoptive cell transfer of tumor-infiltrating lymphocytes after lymphopenia induction for metastatic melanoma. *J Immunother* 35(8):615-620, 2012. **Co-author.**
45. Veerapathran, A., Pidala, J, Beato, F, Betts, B, Kim, J, Turner, JG, Hellerstein, MK, Yu, X-Z, **Janssen, W**, Anasetti, C. Human regulatory T cells against minor histocompatibility antigens: ex vivo expansion for prevention of graft-versus-host disease. *Blood* 122(13):2251-2261, 2013. **Co-senior author.**
46. Dominici, M., K. Nichols, A. Srivastava, D.J. Weiss, P. Eldridge, N. Cuende, R.J. Deans, J.E. Rasko, A.D. Levine, L. Turner, D.L. Griffin, L. O'Donnell, M. Forte, C. Mason, E. Wagena, **W.**



- Janssen**, R. Nordon, D. Wall, H.N. Ho, M.A. Ruiz, S. Wilton, E.M. Horwitz, K.C. Gunter, and I.P.T.F.o.U.C. Therapy, *Positioning a Scientific Community on Unproven Cellular Therapies: The 2015 International Society for Cellular Therapy Perspective*. *Cytotherapy*, . **17**: 1663-1666. 2015. **Co-author**.
47. Eldridge, P., D. Griffin, **W. Janssen**, and L. O'Donnell, *Part 3: Understanding the manufacturing of unproven cellular therapy products*. *Cytotherapy*, **18**: 124-126. 2016. **Co-author**.
  48. Nichols, K., **W. Janssen**, D. Wall, N. Cuende, and D. Griffin, *Part 4: Interaction between unproven cellular therapies and global medicinal product approval regulatory frameworks*. *Cytotherapy*, **18**: 127-137. 2016. **Co-author**.
  49. Talleur AC, Triplett BM, Federico S, Mamcarz E, **Janssen W**, Wu J, Shook D, Leung W, Furman WL. *Consolidation Therapy for Newly Diagnosed Pediatric Patients with High-Risk Neuroblastoma Using Busulfan/Melphalan, Autologous Hematopoietic Cell Transplantation, Anti-GD2 Antibody, Granulocyte-Macrophage Colony-Stimulating Factor, Interleukin-2, and Haploidentical Natural Killer Cells*. *Biol Blood Marrow Transplant*. 23:1910-1917. 2017. **Co-author**.
  50. Federico SM, McCarville MB, Shulkin BL, Sondel PM, Hank JA, Hutson P, Meagher M, Shafer A, Ng CY, Leung W, **Janssen WE**, Wu J, Mao S, Brennan RC, Santana VM, Pappo AS, Furman WL. *A Pilot Trial of Humanized Anti-GD2 Monoclonal Antibody (hu14.18K322A) with Chemotherapy and Natural Killer Cells in Children with Recurrent/Refractory Neuroblastoma*. *Clin Cancer Res*.23:6441-6449. 2017. **Co-author**.
  51. Triplett BM, Muller B, Kang G, Li Y, Cross SJ, Moen J, Cunningham L, **Janssen W**, Mamcarz E, Shook DR, Srinivasan A, Choi J, Hayden RT, Leung W. *Selective T-cell depletion targeting CD45RA reduces viremia and enhances early T-cell recovery compared with CD3-targeted T-cell depletion*. *Transpl Infect Dis*. 20(1):online publication. 2018. **Co-author**.
  52. Nguyen, R., H. Wu, S. Pounds, H. Inaba, R. C. Ribeiro, D. Cullins, B. Rooney, T. Bell, N. J. Lacayo, K. Heym, B. Degar, D. Schiff, **W. E. Janssen**, B. Triplett, C. H. Pui, W. Leung and J. E. Rubnitz (2019). "A phase II clinical trial of adoptive transfer of haploidentical natural killer cells for consolidation therapy of pediatric acute myeloid leukemia." *Journal for immunotherapy of cancer* **7**(1): 81. **Co-author**.
  53. Mamcarz E, Zhou S, Lockey T, Abdelsamed H, Cross SJ, Kang G, Ma Z, Condori J, Dowdy J, Triplett B, Li C, Maron G, Becerra JCA, Church JA, Dokmeci E, Love JT, da Matta Ain AC, van der Watt H, Tang X, **Janssen W**, Ryu BY, De Ravin SS, Weiss MJ, Youngblood B, Long-Boyle JR, Gottschalk S, Meagher MM, Malech HL, Puck JM, Cowan MJ, Sorrentino BP (2019). *Lentiviral Gene Therapy with Low Dose Busulfan for Infants with X-SCID*. *N Engl J Med*. 2019 Apr 18;380(16):1525-1534. **Co-author**.

**ii. Original Research Articles Accepted for Future Publication:**

None.

**iii. Reviews and Conference Proceedings:**

1. **Janssen W**. Data management in the cell therapy production facility: the batch process record (BPR). *Cytotherapy* 10:227-237, 2008. **First author. Review Article**.

## B. Non-peer reviewed publications and reports:

### i. Book Chapters and Monographs:

1. **Janssen WE**, Lee C. Transportation of bone marrow for in vitro processing and transplantation. In: Bone Marrow Processing and Purging: A Practical Guide. (Gee AP, ed.) CRC Press, Inc. Boca Raton, FL; pp 39-52, 1991. **First author, senior author.**
2. **Janssen WE**, Elfenbein GJ. Mobilization of peripheral blood stem cells: Are all regimens created equal? In: Hematopoietic Stem Cells: Biology and Therapeutic Applications. (Levitt/Mertelsmann, eds.) Marcel Dekker, New York; pp 403-420, 1995. **First author.**

### ii Reviews and Conference Proceedings

1. Gee AP, Lee C, Bruce K, **Janssen W**, Graham-Pole J, Pawlina T, Pick T, Harvey W, Koch P, Gross S. Immunomagnetic purging and autologous transplantation in stage D neuroblastoma. Bone Marrow Transplant 2(suppl. 2):89-93, 1987. **Co-author. Invited.**
2. Fort JA, Rios AM, Gross S, **Janssen WE**. CD9 is an unreliable antibody for bone marrow purging. Prog Clin Biol Res 333:185-189, 1990 **Co-author.. Submitted.**
3. **Janssen WE**, Gee AP, Graham-Pole JR, Lee C, Luzins J, Spencer C, Worthington-White DA, Pick T, Koch P, Gross S. Transporting bone marrow for in vitro purging before autologous reinfusion. Prog Clin Biol Res 333:541-549, 1990. **First author. Submitted.**
4. **Janssen WE**, Lee C, Johnson KS, Spencer C, Rios AM, Graham-Pole JR, Gross S. Immunomagnetic microsphere mediated purging of cALLa positive leukemic cells from bone marrow for autologous reinfusion. Prog Clin Biol Res 333:285-292, 1990. **First author. Submitted.**
5. Kedar A, Schreier H, Rios AM, **Janssen WE**, Gross S. Lipid coating of paramagnetic microspheres reduces non-specific binding to Kelly neuroblastoma cells. Prog Clin Biol Res 333:293-301, 1990. **Co-author. Submitted.**
6. **Janssen WE**, Benson K, Lee C, Noll L, Smilee R, Fields KK, Zorsky PE, Elfenbein GJ. Salvage and transfusion of autologous red blood cells from bone marrow harvest. Prog Clin Biol Res 377:337-344, 1992. **First author. Submitted.**
7. **Janssen WE**, Lee C, Farmelo MJ, Smilee R, Barth K, Fields KK, Zorsky PE, Elfenbein GJ. Use of CD34+ cell fraction as a measure of hematopoietic stem cells in bone marrow and peripheral blood: comparison with the CFU-GM assay. Prog Clin Biol Res 377:513-521, 1992. **First author. Submitted.**
8. **Janssen WE**, Smilee R, Carter R, Rahn D, Cairo M, Hiemenz JH, Zorsky PE, Fields KK, Ballester O, Perkins J, et al. Mobilization of peripheral blood stem cells: comparing cyclophosphamide and growth factor based regimens. Prog Clin Biol Res 389:429-439, 1994. **First author. Submitted.**
9. Elfenbein GJ, **Janssen WE**, Perkins JB. Relative contributions of marrow microenvironment, growth factors, and stem cells to hematopoiesis in vivo in man. Review of results from autologous stem cell transplant trials and laboratory studies at the Moffitt Cancer Center. Ann NY Acad Sci 770:315-338, 1995. **Co-first author. Invited.**
10. **Janssen WE**, Elfenbein GJ, Fields KK, Hiemenz JW, Zorsky PE, Ballester OF, Goldstein SC, Smilee R, Kronish L, Beach B, LeParc G. Comparison of cell collections and rates of post-transplant granulocyte recovery when G-CSF and GM-CSF are used as mobilizers of peripheral blood stem cells for autotransplantation. In: Autologous Bone Marrow Transplantation, Proceedings of the 7th International Symposium. (Dicke KA, Keating A, Eds.) Arlington, TX; pp 527-540, 1995. **First author. Submitted.**

11. **Janssen WE.** Mobilization of peripheral blood stem cells for autologous transplantation. Methods, mechanisms, and role in accelerating hematopoietic recovery. *Ann NY Acad Sci* 770:116-129, 1995. **First author. Invited.**
12. Elfenbein GJ, **Janssen WE**, Perkins JB, Partyka JS, Fields KK. Mathematical modeling of human hematopoiesis: Lessons learned from the bedside following autologous peripheral blood stem cell transplants. *Autologous Blood and Marrow Transplantation*, Proceedings of the 8th International Symposium. (Dicke KA, Keating A, Eds.) Arlington, TX; 1996. **Co-first author. Submitted.**

### 13. Presentations

#### A. Poster Presentations (Last three years only – Not showing if full manuscript published).

1. Law P, Triplett B, Leung W, Kang G, **Janssen W.** *Factors Affecting Clinimacs Enrichment of CD34+ Cells from Peripheral Blood Stem Cell Products: A Single Center Analysis of 278 Procedures.* International Society for Cell Therapy, May 2016. **Senior author.**
2. **Janssen W**, Davis K, Hale J, Alloush L, Hu X, Porter E, Hughes C, Harjes K, Schoultz S. *A Simple Large Scale Method for T Cell Enrichment by Negative Selection in Preparation for Viral Transduction.* International Society for Cell Therapy, May 2017. **First author, senior author.**
3. Tsang KS, Law P, Sunkara A, Triplett B, Srinivasan A, Leung W, Kang G, Eldridge P, **Janssen W.** *Haploidentical Natural Killer Cell Therapy: Analysis of 205 Clinimacs Procedures of CD3 Depletion Followed by CD56 Selection.* International Society for Cell Therapy, May 2017. **Senior author.**
4. Davis K, Alloush L, Hale J, Ribickas AJ, Kelley L, **Janssen W.** *Haemonetics Cell Saver as a Laboratory Cell Processing Instrument: Fine Tuning Buffy Coat Processing.* International Society for Cell and Gene Therapy, May 2018. **Senior author.**
5. **Janssen W**, Alloush L, Davis K, Hale J, Hu X, Hughes C, Jones B, Mastio-Partridge C-L, Porter V, Ruffin K, Schoultz S. *Linear Relationship of Cells In vs. Cells Out With The Clinimacs Plus.* International Society for Cell and Gene Therapy, May 2018. **First author, senior author.**
6. Ribickas AJ, Thigpen S, **Janssen WE**, Kelley LL. *An Automated Method of Enrichment of Lymphocytes from Apheresis Products for Cellular Engineering.* International Society for Cell and Gene Therapy, May 2018. **Co-senior author.**

### 14. Other Creative Products

**Investigational New Drug (IND) and Investigational Device Exemption (IDE) submitted and approved by US Food and Drug Administration. For all of the below, William Janssen directed and compiled pre-clinical testing of methods, wrote introductory, CMC, and human subject experience and development plan sections. William Janssen contributed to clinical protocols and pharm-tox sections, and was responsible for final compilation, submission and management of the approval process:**

#### INDs / IDEs Submitted from Moffitt Cancer Center

BB-IND-7952	Adenovirus vectored human B7.1 gene modified renal cell carcinoma autologous tumor cell vaccine. July 1999.
BB-IND-9792	P53 modified adenovirus transduced dendritic cell vaccine. May 2001.

BB-IND-9854	ALVAC human B7.1 gene modified renal cell carcinoma autologous tumor cell vaccine. December 2001.
BB-IDE-9913	Segregated CD34 negative primary graft donor leukocyte infusion. September 2001.
BB-IND-10005	Cultured dendritic cells for direct intratumoral injection. September 2001.
BB-IND-10797	K562 modified to secrete GM-CSF and express CD40 ligand to be used with autologous tumor cells as an anti-tumor vaccine. April 2003.
BB-IND-12707	Autologous tumor lysate and KLH loaded dendritic cells. October 2005.
BB-IND-13036	KLH pulsed dendritic cells for intratumoral administration following treatment with adenovirus vectored TNF-alpha gene. May 2006.
BB-IND-13088	K562 modified to secrete GM-CSF and express CD40 ligand used concomitantly with allogeneic non-small cell lung cancer cell lines as anti-tumor vaccine. July 2006.
BB-IND-13325	P53 modified adenovirus transduced dendritic cell vaccine used in conjunction with high dose cytotoxic therapy and hematopoietic progenitor transplant and infusion of expanded autologous T-lymphocytes. March 2007.
BB-IND-13478	K562 modified to secrete GM-CSF and express CD40 ligand used concomitantly with lenalidomide in the treatment of MDS. May 2007.
BB-IND-13483	Dendritic cells pulsed with class I and class II associated peptides and KLH, and infected with systemic lymphocyte chemokine (CCL-21) modified adenovirus. August 2007.
BB-IND-14013	Lymphodepletion followed by tumor infiltrating lymphocytes in the treatment of melanoma. December 2010.
BB-IND-14664	GM-CSF secreting / CD40 ligand expressing bystander cells combined with CCL-21 modified H-1944 lung cancer cell line and unmodified H-2122 lung cancer cell line as vaccine. May 2011.
BB-IND-15233	Allogeneic T cells derived from peripheral blood mononuclear cells (CD25+, Miltenyi) cultured with recipient dendritic cells, IL2, IL15 and rapamycin. August 2012.
BB-IND-15395	Tumor lysate pulsed dendritic cells for use following autologous HPC transplant in the treatment of neuroblastoma. February 2013.

#### **INDs / IDEs Submitted from St. Jude Children's Research Hospital**

BB-IDE-18136	Haplocompatible Transplant Using TCR $\alpha/\beta$ Depletion Followed by CD45RA-Depleted Donor Lymphocyte Infusions for Severe Combined Immunodeficiency (SCID). April 2018.
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