BIOGRAPHICAL SKETCH

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NAME: Richardson, Paul G

eRA COMMONS USER NAME (credential, e.g., agency login): PAUL_RICHARDSON

POSITION TITLE: Professor of Medicine

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Medical College of St. Bartholomew's Hospital, University of London, London, United Kingdom	MBBS	1986	Medicine
Harvard University	MA	2012	Medicine

Personal Statement

After certification in Internal Medicine, Hematology and Medical Oncology, as well as working in Cancer Pharmacology from 1994 onwards at Dana-Farber Cancer Institute (DFCI), Dr. Paul Richardson joined the Jerome Lipper Myeloma Center in 1999, was appointed Clinical Director in 2001, and led the development of several first-generation novel drugs including bortezomib, lenalidomide and pomalidomide for the treatment of multiple myeloma. Subsequent studies have focused on next generation novel drugs including panobinostat and second-generation proteasome inhibitors including ixazomib. More recently, his clinical innovations have been in the development of the breakthrough monoclonal antibodies elotuzumab and daratumumab for the treatment of both untreated and relapsed myeloma, as well as isatuximab and more broadly, antibody drug conjugates including belantamab mafodotin, as well as other immunotherapeutic strategies. In addition to these agents, he is leading the development of melflufen, a novel peptide drug conjugate and a first-in-class small molecule inhibitor selinexor, which targets XPO-1, a key nuclear export protein, as well as first-in-human studies of potent cereblon E3 ligase modulators (so called CELMoDs) for the treatment of relapsed and refractory myeloma.

He has published extensively, having authored or co-authored over 450 original articles and 375 reviews, chapters, and editorials in peer-reviewed journals. In addition to holding positions on the Editorial Boards of leading journals, he is prior Chairman of the Multiple Myeloma Research Consortium (MMRC), Clinical Trials Core, a position held for 5 years as part of a rotating tenure, and for which he continues as a member of the Steering and Project Review Committee. He was also a member of ASCO Hematologic Malignancies Subcommittee for the required one-year term, and then for one year on the ASCO Internet Cancer Information Committee during 2017. He was appointed Chair of the Alliance Myeloma Committee in 2011 and completed his 10-year tenure in this role in 2021.

Honors include the George Canellos Award for Excellence in Clinical Research and Patient Care, and The Tisch Outstanding Achievement Award for Clinical Research, as well an honorary Fellowship of the Royal College of Physicians (UK), given in recognition for international contributions in multiple myeloma and stem cell transplantation. He was a co-recipient of the prestigious Warren Alpert Foundation Prize in recognition of the successful therapeutic targeting of the ubiquitin-proteasome pathway in 2012. He was also a co-recipient of the Accelerator Award for contributions to clinical research and patient enrollment in MMRC studies, as well as for the Research Center of the Year Award in 2009, followed by a second award for Center of the Year in 2017. He was ranked by Thomson Reuters Science Watch amongst the top 19 investigators at DFCI for the most highly cited research in 2016. He was the co-recipient of the ASH Ernest Beutler Prize for clinical science and translational research in the development of proteasome inhibition as an effective treatment strategy for multiple myeloma in 2015; the COMY Award for MM research (Paris, France) in 2016, and the

prestigious IMF Robert A. Kyle Lifetime Achievement Award in 2017, together with the Clare and Richard Morse Research Award (DFCI) in 2019, as well as the Giants of Cancer Care Award (USA) in 2021.

1. **Richardson PG**, Sonneveld P, Schuster MW, et al. Assessment of Proteasome Inhibition for Extending Remissions (APEX) Investigators. Bortezomib or high-dose dexamethasone for relapsed multiple myeloma. *N Engl J Med*. 2005 Jun 16;352(24):2487-98. PMID: 15958804
2. **Richardson PG**, Weller E, Lonial S, et al. Lenalidomide, bortezomib, and dexamethasone combination therapy in patients with newly diagnosed multiple myeloma. *Blood*. 2010 Aug 5;116(5):679-86. PMID: 20385792
3. **Richardson PG**, Siegel DS, Vij R, et al. Pomalidomide alone or in combination with low-dose dexamethasone in relapsed and refractory multiple myeloma: a randomized phase 2 study. *Blood*. 2014 Mar 20;123(12):1826-32. PMID: 24421329
4. **Richardson PG**, Oriol A, Beksac M, et al. Pomalidomide, bortezomib, and dexamethasone for patients with relapsed or refractory multiple myeloma previously treated with lenalidomide (OPTIMISMM): a randomised, open-label, phase 3 trial. *Lancet Oncol.* 2019 Jun; 20(6):781-794. Epub 2019 May 13. PMID: 31097405

B. Positions and Honors

Positions and Employment

2014 -	Clinical Program Leader, Director of Clinical Research, Jerome Lipper Multiple Myeloma Center, DFCI, Boston, MA
2012 -	RJ Corman Professor of Medicine, Harvard Medical School, DFCI, Boston, MA
2006 -	Associate Professor of Medicine, Harvard Medical School, DFCI, Boston MA
2003 – 2006	Assistant Professor of Medicine, Harvard Medical School, DFCI, Boston, MA
2001 – 2014	Clinical Director, Jerome Lipper Multiple Myeloma Center, DFCI, Boston, MA
1994 – 2003	Instructor of Medicine, Harvard Medical School, DFCI, Boston, MA
1993 – 1994	Visiting Fellow, Division of Medical Oncology, Department of Medicine, DFCI, Boston, MA
1991 – 1994	Clinical Fellow, Division of Hematology and Oncology, Department of Medicine, Tufts University School of Medicine, Baystate Medical Center, Springfield, MA
1995 – 1997	[Resident] Department of Medicine, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA
1990 – 1991	[Chief Resident] Senior House Officer, Department of Medicine Royal Marsden Hospital, London and Surrey, UK
1987 – 1990	[Senior Resident] Senior House Officer, Department of Medicine, Newcastle University School of Medicine Newcastle General and Freeman Hospitals, Newcastle-upon-Tyne, UK
1986 – 1987	[Intern] Pre-registration House Surgeon and Physician, Departments of Medicine & Surgery, St. Bartholomew's Hospital, University of London, UK

Other Experience and Professional Memberships

2014-	Member, Multiple Myeloma Sub-Committee, Clinical Trials Network (CTN), ASBMT
2013-	Committee Member, Executive Committee for Clinical Research, DFCI
2012-	Scientific Steering Committee Member, NCI Multiple Myeloma Committee
2011-	Chairman, Myeloma Committee, Alliance for Clinical Trials in Oncology
2008-2014	Co-Chairman, Independent Review Committee (IRC), Carfilzomib studies in relapsed MM
2007-2009	Chairman, Data Management and Safety Board (DMSB), Pediatric Study of Defibrotide as Prophylaxis against VOD in Stem Cell Transplant Recipients; a Randomized, Controlled Trial, European Group for Blood and Marrow Transplantation (EBMT)
2006	VOD/SOSS Subcommittee, Member, State of the Science Symposium, Blood and Bone Marrow Transplant, Clinical Trials Network (NHLBI/NCI)
2006	American Society of Hematology/Food and Drug Administration, Multiple Myeloma (MM) Committee Member and Sub-Committee Chairman, Special Task Force for Impending Drug Approval
2005	American Society of Clinical Oncology (ASCO) Research Committee
2004-2009	Multiple Myeloma Research Consortium (MMRC), Chairman, Clinical CORE
2001-2009	Institutional Review Board, Member, DFCI

1999 American College of Physicians
1997 American Society of Hematology, Member
1995 American Society of Clinical Oncology, Member

Honors

2019 Morse Research Award
2017 Robert A. Kyle Lifetime Achievement Award, International Myeloma Foundation
2016 Multiple Myeloma Achievement Award, 2nd World Congress on Controversies in multiple myeloma
2015 Ernest Beutler Lecture and Prize, American Society of Hematology
2012 Warren Alpert Foundation Prize, Harvard Medical School
2009 Fellowship of the Royal College of Physicians (FRCP), London, UK
2008 Schwartz Cancer Center Compassionate Caregiver Award
2008 Tisch Family Outstanding Achievement Award in Translational Research
2006 Partners in Excellence Award, DFCI
2004 Partners in Excellence Award, DFCI
2004 George Canellos Award for Excellence in Clinical Research and Patient Care, DFCI
2002 The Society of Teaching Scholars, Brigham and Women's Hospital
1997 Lee Beckenstein Fellowship Award
1995 Emil Frei III Fellowship Award

C. Contribution to Science

1. *New drug development in multiple myeloma*. Novel agents in the treatment of multiple myeloma have resulted in significant improvements in overall survival and patient outcome. My contributions in this area have included the development of bortezomib, and then lenalidomide as a key immunomodulatory agent in the treatment of the disease, as well as the subsequent development of pomalidomide as a next-generation immunomodulatory drug after lenalidomide failure. Further, the development of ixazomib as the first oral boronate peptide has been an important contribution in this setting, as well as most recently selinexor and melflufen.
    a. **Richardson PG**, Siegel D, Baz R, et al. Phase 1 study of pomalidomide MTD, safety, and efficacy in patients with refractory multiple myeloma who have received lenalidomide and bortezomib. *Blood*. 2013 Mar 14;121(11):1961-7. PMID: 23243282
    b. **Richardson PG**, Baz R, Wang M, et al. Phase 1 study of twice-weekly ixazomib, an oral proteasome inhibitor, in relapsed/refractory multiple myeloma patients. *Blood*. 2014 Aug 14;124(7):1038-46. PMID: 24920586
    c. Chari A, Vogl DT, Gavriatopoulou M, Nooka AK, Yee AJ, Huff CA, Moreau P, Dingli D, Cole C, Lonial S, Dimopoulos M, Stewart AK, Richter J, Vij R, Tuchman S, Raab MS, Weisel KC, Delforge M, Cornell RF, Kaminetzky D, Hoffman JE, Costa LJ, Parker TL, Levy M, Schreder M, Meuleman N, Frenzel L, Mohty M, Choquet S, Schiller G, Comenzo RL, Engelhardt M, Illmer T, Vlummens P, Doyen C, Facon T, Karlin L, Perrot A, Podar K, Kauffman MG, Shacham S, Li L, Tang S, Picklesimer C, Saint-Martin JR, Crochiere M, Chang H, Parekh S, Landesman Y, Shah J, **Richardson PG**, Jagannath S. Oral Selinexor-Dexamethasone for Triple-Class Refractory Multiple Myeloma. *N Engl J Med*. 2019 Aug 22;381(8):727-38.
    d. **Richardson PG,** Bringhen S, Voorhees P, Plesner T, Mellqvist UH, Reeves B, Paba-Prada C, Zubair H, Byrne C, Chauhan D, Anderson K, Nordström E, Harmenberg J, Palumbo A, Sonneveld P. Melflufen plus dexamethasone in relapsed and refractory multiple myeloma (O-12-M1): a multicentre, international, open-label, phase 1-2 study. *Lancet Haematol*. 2020 Mar 23. doi: 10.1016/S2352-3026(20)30044-2. [Epub ahead of print]

2. *Novel combinations in multiple myeloma.* In the context of novel treatments for multiple myeloma improving outcome, combinatorial strategies have been critical. These have typically been informed by laboratory studies. Examples include the combination of lenalidomide and bortezomib, and studies have included histone deacetylase inhibitors in combination with other backbone agents. The development of ixazomib and its combination with lenalidomide and dexamethasone has resulted in a highly effective regimen in the upfront setting and has been extensively tested in the relapsed and refractory setting as part of the TOURMALINE program. Marizomib as a next generation proteasome

inhibitor and with greater potency than either boronate peptides and epoxyketones is similarly in development.

a. Moreau P, Masszi T, Grzasko N, Bahlis NJ, Hansson M, Pour L, Sandhu I, Ganly P, Baker BW, Jackson SR, Stoppa AM, Simpson DR, Gimsing P, Palumbo A, Garderet L, Cavo M, Kumar S, Touzeau C, Buadi FK, Laubach JP, Berg DT, Lin J, Di Bacco A, Hui AM, van de Velde H, **Richardson PG**. Oral Ixazomib, Lenalidomide, and Dexamethasone for Multiple Myeloma. *N Engl J Med*. 2016 Apr 28;374(17):1621-34. PMID: 27119237
b. **Richardson PG**, Zimmerman TM, Hofmeister CC, et al. Phase 1 study of marizomib in relapsed or relapsed and refractory multiple myeloma: NPI-0052-101 Part 1. *Blood*. 2016 Jun 2;127(22):2693-700. PMID: 27009059
c. **Richardson PG,** Hofmeister CC, Raje NS, Siegel DS, Lonial S, Laubach J, Efebera YA, Vesole DH, Nooka AK, Rosenblatt J, Doss D, Zaki MH, Bensmaine A, Herring J, Li Y, Watkins L, Chen MS, Anderson KC. Pomalidomide, bortezomib and low-dose dexamethasone in lenalidomide-refractory and proteasome inhibitor-exposed myeloma. *Leukemia*. 2017 Dec;31(12):2695-2701. PMID: 28642620
d. Spencer A, Harrison S, Zonder J, Badros A, Laubach J, Bergin K, Khot A, Zimmerman T, Chauhan D, Levin N, MacLaren A, Reich SD, Trikha M, **Richardson PG**. A phase 1 clinical trial evaluating marizomib, pomalidomide and low-dose dexamethasone in relapsed and refractory multiple myeloma (NPI-0052-107): final study results. *Br J Haematol.* 2018 Jan;180(1):41-51. PMID: 29076150

3. *Immuno-therapeutics in multiple myeloma.* A key barrier to success in the treatment of multiple myeloma has been immune-paresis. Moreover, the integration of monoclonal antibody therapy has been a key area of progress in developmental therapeutics. In this regard, I have provided leadership in the development of daratumumab as well as elotuzumab as a breakthrough treatment, and most recently belantamab mafodotin and isatuximab.
    a. **Richardson PG,** Jagannath S, Moreau P, et al. Elotuzumab in combination with lenalidomide and dexamethasone in patients with relapsed multiple myeloma: final results from the 1703 phase 1b/2, open-label, randomised study. *Lancet Haematol.* 2015 Dec;2(12):e516-27. PMID: 26686406
    b. Plesner T, Arkenau HT, Gimsing P, Krejcik J, Lemech C, Minnema MC, Lassen U, Laubach JP, Palumbo A, Lisby S, Basse L, Wang J, Sasser AK, Guckert ME, de Boer C, Khokhar NZ, Yeh H, Clemens PL, Ahmadi T, Lokhorst HM, **Richardson PG**. Phase 1/2 study of daratumumab, lenalidomide, and dexamethasone for relapsed multiple myeloma. *Blood*. 2016 Oct 6;128(14):1821-1828. PMID: 27531679
    c. Plesner T, Arkenau HT, Gay F, Minnema MC, Boccadoro M, Moreau P, Cavenagh J, Perrot A, Laubach JP, Krejcik J, Ahmadi T, de Boer C, Chen D, Chiu C, Schecter JM, **Richardson PG.** Enduring efficacy and tolerability of daratumumab in combination with lenalidomide and dexamethasone in patients with relapsed or relapsed/refractory multiple myeloma (GEN503): final results of an open-label, phase 1/2 study. *Br J Haematol.* 2019 Mar 31. doi: 10.1111/bjh.15879. PMID: 30931524
    d. **Richardson PG**, Attal M, Rajkumar SV, San-Miguel J, Beksac M, Spicka I, Leleu X, Schjesvold F, Moreau P, Dimopoulos MA, Shang-Yi Huang J, Minarik J, Cavo M, Prince HM, Mace S, Corzo KP, Campana F, Le-Guennec S, Dubin F, Anderson KC on behalf of the ICARIA-MM study group. A phase 3 randomized, open-label, multicenter study comparing isatuximab, pomalidomide, and low-dose dexamethasone versus pomalidomide and low-dose dexamethasone in patients with relapsed/refractory multiple myeloma. Proceedings of the 24th Congress of the European Hematology Association; 2019 June 13-16; Amsterdam, Netherlands. *Haematologica*. 2019; [epub ahead of print] [abstract S824].

4. *Integration of stem cell transplantation in the management of younger patients with multiple myeloma.* With the advent of the novel agents as well as monoclonal antibodies, the position of autologous stem cell transplantation in the management of younger multiple myeloma patients has become a critical question. The pivotal IFM/DFCI 2009 study examining the role of early versus late transplant with a comprehensive examination of both patient and disease characteristics is the current leading trial examining this question. The development of highly effective upfront induction strategies as well as the

integration of maintenance and consolidation has been a vital part of the process. Moreover, the development of other combinations (including all oral approaches) provide important forward directions in the future.

a. Attal M, Lauwers-Cances V, Hulin C, Leleu X, Caillot D, Escoffre M, Arnulf B, Macro M, Belhadj K, Garderet L, Roussel M, Payen C, Mathiot C, Fermand JP, Meuleman N, Rollet S, Maglio ME, Zeytoonjian AA, Weller EA, Munshi N, Anderson KC, **Richardson PG**, et al. Lenalidomide, Bortezomib, and Dexamethasone with Transplantation for Myeloma. *N Engl J Med*. 2017 Apr 6;376(14):1311-1320. PMID: 28379796
b. Perrot A, Lauwers-Cances V, Corre J, Robillard N, Hulin C, Chretien ML, Dejoie T, Majeo S, Stoppa AM, Pegourie B, Karlin L, Garderet L, Arnulf B, Doyen C, Meuleman N, Royer B, Eveillard JR, Benboubker L, Dib M, Decaux O, Jaccard A, Belhadj K, Brechignac S, Kolb B, Fohrer C, Mohty M, Macro M, **Richardson PG,** Carlton V, Moorhead M, Willis T, Faham M, Anderson KC, Harousseau JL, Leleu X, Facon T, Moreau P, Attal M, Avet-Loiseau H, Munshi N. Minimal residual disease negativity using deep sequencing is a major prognostic factor in multiple myeloma*. Blood.* 2018 Dec 6;132(23):2456-64. PMID: 28444784
c. Kazandjian D, Mo CC, Landgren O, **Richardson PG**. The role of high-dose melphalan with autologous stem-cell transplant in multiple myeloma: is it time for a paradigm shift? *Br J Haematol*. 2020 Jun 5. doi: 10.1111/bjh.16764.[Epub ahead of print]

5. *Management of toxicities in multiple myeloma and other settings.* Critical to improving outcome in patients with multiple myeloma has been improving the tolerability of therapy. This is particularly true in the management of peripheral neuropathy in which I have led comprehensive efforts to examine the neurotoxicity of bortezomib prospectively and generate effective treatment strategies. In the context of autologous stem cell transplantation and allogeneic transplant, one of the barriers to cure has been fatal regimen-related toxicities associated with conditioning and endothelial damage. My research efforts in this area have resulted in the development of defibrotide for the treatment of veno-occlusive disease and sinusoidal obstruction syndrome with this agent. This agent may also prove effective in other microangiopathies associated with transplant. Moreover, there may also be an emerging role for this drug to abrogate the vascular complications associated with graft versus host disease.
    a. **Richardson PG**, Delforge M, Beksac M, et al. Management of treatment-emergent peripheral neuropathy in multiple myeloma. *Leukemia*. 2012 Apr;26(4):595-608. PMID:22193964
    b. **Richardson PG**, Riches ML, Kernan NA, et al. Phase 3 trial of defibrotide for the treatment of severe veno-occlusive disease and multi-organ failure. *Blood*. 2016 Mar 31;127(13):1656-65. PMID: 26825712
    c. **Richardson PG**, Smith AR, Triplett BM, et al. Earlier defibrotide initiation post-diagnosis of veno-occlusive disease/sinusoidal obstruction syndrome improves Day +100 survival following haematopoietic stem cell transplantation. *Br J Haematol*. 2017 Jul;178(1):112-118. doi: 10.1111/bjh.14727. Epub 2017 Apr 26. PMID: 28444784
    d. **Richardson PG**, Smith AR, Kernan NA, Lehmann L, Soiffer RJ, Ryan RJ, Tappe W, Grupp S. Pooled analysis of Day 100 survival for defibrotide-treated patients with hepatic veno-occlusive disease/sinusoidal obstruction syndrome and ventilator or dialysis dependence following haematopoietic cell transplantation. *Br J Haematol*. 2020 Mar 10. doi: 10.1111/bjh.16552. [Epub ahead of print]

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