
BIOGRAPHICAL SKETCH

NAME: Jesús Fernando San Miguel Izquierdo

POSITION TITLE: Professor of Medicine and Senior Consultant at Cancer Center Clínica Universidad de Navarra

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Navarra	MD	1976	Medicine
University of Salamanca	PhD	1980	Hematology

A. Personal Statement

Jesús San-Miguel, MD, PhD is currently Senior Consultant at the Cancer Center Clínica Universidad de Navarra and Professor of Medicine. He has been Director of Clinical and Translational Medicine at the University of Navarra and Medical Director of the Clínica Universidad de Navarra from 2013 until last August 2023. He served as director of the Hematology Department of the University Hospital of Salamanca in Spain for more than two decades. He was also President of the International Myeloma Society from 2012 until 2019. The international reputation of Prof. San Miguel is supported by the quality of the >950 PAPERS published in top peer-reviewed journals with an H INDEX OF 127, together with 120 BOOK CHAPTERS and monographs. Sum of times cited: 68588. He has presented >200 invited lectures including the educational programs of the European and American Hematology Societies and the American Society of Clinical Oncology. Nevertheless, perhaps his most relevant feature is the ability to integrate the clinic and the bench in a translational research model to serve the patient. This is reflected in the following contributions, summarized as five MILESTONES that Impacted Clinical Practice:

1) Leadership role in pivotal studies for new anti-myeloma drugs in preclinical and clinical settings that led to the APPROVAL OF 4 DRUG COMBINATIONS by EMA & FDA: bortezomib-MP, panobinostat-VP, pomalidomide-Dex, and daratumumab-VMP, and the first CAR-T cell for Myeloma (Ide-Cel).

2) Introduction of the concept of "early diagnosis and intervention in smoldering myeloma" that led to a CHANGE IN THE DIAGNOSTIC CRITERIA of multiple myeloma.

3) The establishment of CENTRALIZED UNITS FOR THE DIAGNOSIS AND MONITORING of hematological malignancies (>80.000 patients have benefited from the studies performed at these units), with special leadership in the area of immunophenotyping and minimal residual disease (pioneering this concept in acute leukemia and myeloma). THIS HAS CHANGED THE RESPONSE CRITERIA FOR MULTIPLE MYELOMA.

4) A leading role in establishing COOPERATIVE GROUPS AND NETWORKS (at both domestic and international levels) (i.e. the Spanish myeloma group, the European myeloma network, the European network of minimal residual disease, the International Myeloma Working Group...).

5) Passionate, COMMITTED SERVICE TO MEDICAL COMMUNITY AND TO PATIENTS through participation in domestic and international committees and commissions, as well as the conception of numerous (>20) guidelines and consensus papers on diagnosis, classification and treatment. Responsible for the creation of the International Staging System for myeloma (>2000 citations). It should be also highlighted the outstanding reputation achieved by the Spanish Myeloma Group, which he founded, and includes >100 HOSPITALS, allowing patients to have access to uniform treatments through innovative clinical trials. Noteworthy is his long lasting INSTITUTIONAL LEADERSHIP as past Vice-director of the Cancer Center of Salamanca, past Scientific Director of the Biomedical Research Institute of Salamanca (IBSAL); past director of Clinical and Translational

Medicine at the University of Navarra and Scientific Director of CIMA. Finally, his mentorship capacity includes >40 HEMATOLOGISTS AND 40 PhD STUDENTS have been trained under his supervision.

Dr. San Miguel reputation has been recognized by >30 RESEARCH AWARDS AND HONORS such as the Waldenström Award, the Kyle Life Achievement Award (the second European that obtains both distinctions), the EHA-Carreras Award, the Thomas H. Ham-Wasserman Lecture Award, the Michaeli Award (Cornell University & SAS Foundation), the KNAW Bob Pinedo Award (Royal Netherland Academy of Arts & Science), Premio Fundación Lilly, Premio Rey Jaime I and the Spanish National Prize 2021 of Medicine (Gregorio Marañón).

B. Positions, Scientific Appointments, and Honors

Positions and Employment	
1980-1985	ASSISTANT PROFESSOR OF HEMATOLOGY AT THE UNIVERSITY OF SALAMANCA
1985-1995	ASSOCIATE PROFESSOR OF HEMATOLOGY AT THE UNIVERSITY OF SALAMANCA
1987- 1993	NATIONAL COUNCILLOR AT THE INTERNATIONAL SOCIETY OF HEMATOLOGY
1991-2013	HEAD OF HEMATOLOGY DEP. OF THE UNIVERSITY HOSPITAL OF SALAMANCA
1995-2013	FULL PROFESSOR OF HEMATOLOGY AT THE UNIVERSITY OF SALAMANCA
1995-1999	VICE-DIRECTOR OF THE DEPARTMENT OF MEDICINE
1998-2001	DIRECTOR OF STUDIES OF THE UNIVERSITY HOSPITAL OF SALAMANCA
2000-2004	VICE-DIRECTOR OF THE CANCER RESEARCH CENTER OF SALAMANCA
2000-	CO-CHAIRMAN OF THE SPANISH MYELOMA GROUP
2000-	BOARD MEMBER OF THE ROYAL ACADEMY OF MEDICINE OF SALAMANCA
2003-2007	BOARD COUNCILLOR OF THE EUROPEAN HEMATOLOGY ASSOCIATION
2008	FOUNDING MEMBER OF THE EUROPEAN MYELOMA NETWORK
2012-2019	PRESIDENT ELECT OF THE INTERNATIONAL MYELOMA SOCIETY
2013-2023	DIRECTOR OF CLINICAL AND TRANSLATIONAL MEDICINE, UNIVERSITY OF NAVARRA
2013-2023	MEDICAL DIRECTOR OF THE CLINICA UNIVERSIDAD DE NAVARRA
2013-2023	SCIENTIFIC DIRECTOR OF CENTRO DE INVESTIGACION MEDICA APLICADA (CIMA), UNIVERSITY OF NAVARRA
2013-2023	VICE-DEAN OF RESEARCH, MEDICAL FACULTY, UNIVERSITY OF NAVARRA
2013-	FULL PROFESSOR OF MEDICINE, UNIVERSITY OF NAVARRA, SPAIN
Professional Memberships	
	Member of the Spanish Society of Hematology and Hemotherapy (SEHH)
	Member of the International Myeloma Working Group (IMWG)
	Member of the European Hematology Association (EHA)
	Member of the American Society of Hematology (ASH)
Honors	
1990	Honorary citizen of Puebla (México)
1992	Honorary member of the Costa Rica Hematology Society
1999	Prize of the National Academy of Medicine of Argentina to the Latin-American Hematologist with the highest impact factor
2000	Prize of clinical research granted by the Science Health Foundation
2001	Annual prize of Scientific Research in Biomedicine (CEOE)
2002	Award of Merit form the Ministry of Defense for his contribution to study the Balkans syndrome
2007	National Award of Oncology, Severo Ochoa Foundation
2007	National Award of translational research
2007	Waldenström Award
2008	Award of Scientific and Technical Research of Castilla y León region
2012	Robert Kyle life achievement award
2012	Jose Carreras EHA Award
2013	“Rey Jaime I” award for Medical Research
2014	Ham-Wasserman award
2014	Foundation Lilly award for biomedical clinical research
2015	Celgene Career Achievement Award for Clinical Research in Hematology

2016	EBMT Opening Lecture: Multiple Myeloma, Evolution in the Treatment Landscape
2018	Michaeli Award for his contribution to Myeloma” Weill Cornell University and the SASS Foundation for Medical Research Award
2020	KNAW Bob Pinedo Cancer Care Award 2020, from the Royal Netherlands Academy of Arts and Sciences and the Bob Pinedo Cancer Care Foundation
2021	Spanish National Prize of Medicine
2022	Jan Gosta Waldenström Award

C. Contributions to Science

Dr. San Miguel has contributed with nearly 1,000 manuscripts and more than 100 book chapters. The list below of manuscripts below merely reflects some highlights of his career:

1: Dimopoulos MA, Dytfeld D, Grosicki S, Moreau P, Takezako N, Hori M, Leleu X, LeBlanc R, Suzuki K, Raab MS, Richardson PG, Popa McKiver M, Jou YM, Yao D, Das P, **San-Miguel J**. Elotuzumab Plus Pomalidomide and Dexamethasone for Relapsed/Refractory Multiple Myeloma: Final Overall Survival Analysis From the Randomized Phase II ELOQUENT-3 Trial. **J Clin Oncol**. 2022 Aug 12;JCO2102815. doi: 10.1200/JCO.21.02815.

2: Munshi NC, Anderson LD Jr, Shah N, Madduri D, Berdeja J, Lonial S, Raje N, Lin Y, Siegel D, Oriol A, Moreau P, Yakoub-Agha I, Delforge M, Cavo M, Einsele H, Goldschmidt H, Weisel K, Rambaldi A, Reece D, Petrocca F, Massaro M, Connarn JN, Kaiser S, Patel P, Huang L, Campbell TB, Hege K, **San-Miguel J**. Idecabtagene Vicleucel in Relapsed and Refractory Multiple Myeloma. **N Engl J Med**. 2021 Feb 25;384(8):705-716.

3: Mateos MV, Cavo M, Blade J, Dimopoulos MA, Suzuki K, Jakubowiak A, Knop S, Doyen C, Lucio P, Nagy Z, Pour L, Cook M, Grosicki S, Crepaldi A, Liberati AM, Campbell P, Shelekhova T, Yoon SS, Iosava G, Fujisaki T, Garg M, Krevvata M, Chen Y, Wang J, Kudva A, Ukropec J, Wroblewski S, Qi M, Kobos R, **San-Miguel J**. Overall survival with daratumumab, bortezomib, melphalan, and prednisone in newly diagnosed multiple myeloma (ALCYONE): a randomised, open-label, phase 3 trial. **Lancet**. 2020 Jan 11;395(10218):132-141.

4: Dimopoulos MA, Dytfeld D, Grosicki S, Moreau P, Takezako N, Hori M, Leleu X, LeBlanc R, Suzuki K, Raab MS, Richardson PG, Popa McKiver M, Jou YM, Shelat SG, Robbins M, Rafferty B, **San-Miguel J**. Elotuzumab plus Pomalidomide and Dexamethasone for Multiple Myeloma. **N Engl J Med**. 2018 Nov 8;379(19):1811-1822.

5: Mateos MV, Dimopoulos MA, Cavo M, Suzuki K, Jakubowiak A, Knop S, Doyen C, Lucio P, Nagy Z, Kaplan P, Pour L, Cook M, Grosicki S, Crepaldi A, Liberati AM, Campbell P, Shelekhova T, Yoon SS, Iosava G, Fujisaki T, Garg M, Chiu C, Wang J, Carson R, Crist W, Deraedt W, Nguyen H, Qi M, **San-Miguel J**; ALCYONE Trial Investigators. Daratumumab plus Bortezomib, Melphalan, and Prednisone for Untreated Myeloma. **N Engl J Med**. 2018 Feb 8;378(6):518-528.

6: **San-Miguel JF**, Hungria VT, Yoon SS, Beksac M, Dimopoulos MA, Elghandour A, Jedrzejczak WW, Günther A, Nakorn TN, Siritanaratkul N, Schlossman RL, Hou J, Moreau P, Lonial S, Lee JH, Einsele H, Sopala M, Bengoudifa BR, Binlich F, Richardson PG. Overall survival of patients with relapsed multiple myeloma treated with panobinostat or placebo plus bortezomib and dexamethasone (the PANORAMA 1 trial): a randomised, placebo-controlled, phase 3 trial. **Lancet Haematol**. 2016 Nov;3(11):e506-e515.

7: Kumar S, Paiva B, Anderson KC, Durie B, Landgren O, Moreau P, Munshi N, Lonial S, Bladé J, Mateos MV, Dimopoulos M, Kastritis E, Boccadoro M, Orłowski R, Goldschmidt H, Spencer A, Hou J, Chng WJ, Usmani SZ, Zamagni E, Shimizu K, Jagannath S, Johnsen HE, Terpos E, Reiman A, Kyle RA, Sonneveld P, Richardson PG, McCarthy P, Ludwig H, Chen W, Cavo M, Harousseau JL, Lentzsch S, Hillengass J, Palumbo A, Orfao A, Rajkumar SV, **Miguel JS**, Avet-Loiseau H. International Myeloma Working Group consensus criteria for response and minimal residual disease assessment in multiple myeloma. **Lancet Oncol**. 2016 Aug;17(8):e328-e346.

8: Mateos MV, Hernández MT, Giraldo P, de la Rubia J, de Arriba F, Corral LL, Rosiñol L, Paiva B, Palomera L, Bargay J, Oriol A, Prosper F, López J, Arguiñano JM, Quintana N, García JL, Bladé J, Lahuerta JJ, **Miguel JS**.

Lenalidomide plus dexamethasone versus observation in patients with high-risk smouldering multiple myeloma (QuiRedex): long-term follow-up of a randomised, controlled, phase 3 trial. **Lancet Oncol.** 2016 Aug;17(8):1127-1136.

9: Rajkumar SV, Dimopoulos MA, Palumbo A, Blade J, Merlini G, Mateos MV, Kumar S, Hillengass J, Kastritis E, Richardson P, Landgren O, Paiva B, Dispenzieri A, Weiss B, LeLeu X, Zweegman S, Lonial S, Rosinol L, Zamagni E, Jagannath S, Sezer O, Kristinsson SY, Caers J, Usmani SZ, Lahuerta JJ, Johnsen HE, Beksac M, Cavo M, Goldschmidt H, Terpos E, Kyle RA, Anderson KC, Durie BG, **Miguel JF**. International Myeloma Working Group updated criteria for the diagnosis of multiple myeloma. **Lancet Oncol.** 2014 Nov;15(12):e538-48.

10: **San-Miguel JF**, Hungria VT, Yoon SS, Beksac M, Dimopoulos MA, Elghandour A, Jedrzejczak WW, Günther A, Nakorn TN, Siritanaratkul N, Corradini P, Chuncharunee S, Lee JJ, Schlossman RL, Shelekhova T, Yong K, Tan D, Numbenjapon T, Cavenagh JD, Hou J, LeBlanc R, Nahi H, Qiu L, Salwender H, Pulini S, Moreau P, Warzocha K, White D, Bladé J, Chen W, de la Rubia J, Gimsing P, Lonial S, Kaufman JL, Ocio EM, Veskovski L, Sohn SK, Wang MC, Lee JH, Einsele H, Sopala M, Corrado C, Bengoudifa BR, Binlich F, Richardson PG. Panobinostat plus bortezomib and dexamethasone versus placebo plus bortezomib and dexamethasone in patients with relapsed or relapsed and refractory multiple myeloma: a multicentre, randomised, double-blind phase 3 trial. **Lancet Oncol.** 2014 Oct;15(11):1195-206.

11: **San-Miguel JF**, Richardson PG, Günther A, Sezer O, Siegel D, Bladé J, LeBlanc R, Sutherland H, Sopala M, Mishra KK, Mu S, Bourquelot PM, Victoria Mateos M, Anderson KC. Phase Ib study of panobinostat and bortezomib in relapsed or relapsed and refractory multiple myeloma. **J Clin Oncol.** 2013 Oct 10;31(29):3696-703.

12: **Miguel JS**, Weisel K, Moreau P, Lacy M, Song K, Delforge M, Karlin L, Goldschmidt H, Banos A, Oriol A, Alegre A, Chen C, Cavo M, Garderet L, Ivanova V, Martinez-Lopez J, Belch A, Palumbo A, Schey S, Sonneveld P, Yu X, Sternas L, Jacques C, Zaki M, Dimopoulos M. Pomalidomide plus low-dose dexamethasone versus high-dose dexamethasone alone for patients with relapsed and refractory multiple myeloma (MM-003): a randomised, open-label, phase 3 trial. **Lancet Oncol.** 2013 Oct;14(11):1055-1066.

13: Mateos MV, Hernández MT, Giraldo P, de la Rubia J, de Arriba F, López Corral L, Rosiñol L, Paiva B, Palomera L, Bargay J, Oriol A, Prosper F, López J, Olavarria E, Quintana N, García JL, Bladé J, Lahuerta JJ, **San Miguel JF**. Lenalidomide plus dexamethasone for high-risk smoldering multiple myeloma. **N Engl J Med.** 2013 Aug 1;369(5):438-47.

14: **San Miguel JF**, Schlag R, Khuageva NK, Dimopoulos MA, Shpilberg O, Kropff M, Spicka I, Petrucci MT, Palumbo A, Samoilova OS, Dmoszynska A, Abdulkadyrov KM, Delforge M, Jiang B, Mateos MV, Anderson KC, Esseltine DL, Liu K, Deraedt W, Cakana A, van de Velde H, Richardson PG. Persistent overall survival benefit and no increased risk of second malignancies with bortezomib-melphalan-prednisone versus melphalan-prednisone in patients with previously untreated multiple myeloma. **J Clin Oncol.** 2013 Feb 1;31(4):448-55.

15: **San Miguel JF**, Schlag R, Khuageva NK, Dimopoulos MA, Shpilberg O, Kropff M, Spicka I, Petrucci MT, Palumbo A, Samoilova OS, Dmoszynska A, Abdulkadyrov KM, Schots R, Jiang B, Mateos MV, Anderson KC, Esseltine DL, Liu K, Cakana A, van de Velde H, Richardson PG; VISTA Trial Investigators. Bortezomib plus melphalan and prednisone for initial treatment of multiple myeloma. **N Engl J Med.** 2008 Aug 28;359(9):906-17.

List of patents

Enrique M. Ocio; Atanasio Pandiella; Jesús San Miguel; Pablo M. Avilés. 09745841.8 – 2123 PCT/EP2009055978. 2011. MULTIPLE MYELOMA TREATMENTS 2011. Pharma Mar, S.A..

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José A Pérez Simón; Jesús San Miguel Izquierdo. 200502664 PCT/ES2006070155. 2010. USO DE INHIBIDORES DE NF-KB IN VITRO PARA INDUCIR LA DEPLECCIÓN DE LINFOCITOS T ALOREACTIVOS, COMPOSICIONES FARMACEUTICAS DERIVADAS Y USO DE LAS MISMAS Spain. 2010. Universidad de Salamanca.

Diem Mihn; Klaus Strein; Bruno Paiva; Jesús San Miguel. WO2020/089437A1. Combination therapy 31/10/2019. ENGMAB.

Diem Mihn; Klaus Strein; Bruno Paiva; Jesús San Miguel. WO2018/083204 A1. Bispecific antibody against BCMA and CD3 and an immunological drug for combined use in treating multiple myeloma Switzerland. 02/11/2017. ENGMAB.