EUROPEAN
HEALTH FORUM
GASTEIN

Berger, Dietmar
Genentech

Dietmar P. Berger, M.D., Ph.D.

Professional Education

Doctor of Medicine, 1981-1988

Universities of Freiburg (Germany) and Basel (Switzerland), Northwestern University (Chicago, IL). Licensed to practice medicine on 13 May 1988. Doctoral thesis (M.D.) awarded “summa cum laude”.

Internal Medicine, 1989-1995

Residency and Fellowship 1989-1995. Board-certified Internal Medicine (Germany) on 7 April 1995.

Hematology and Oncology, 1989-1997

Residency and Fellowship 1989-1997. Board-certified Hematology and Oncology (Germany) on 22 October 1997.

Professor of Medicine, 1996-today

Habilitation thesis (Germany, Ph.D. equivalent) 25 April 1996, Associate Professorship and authorization to teach (venia legendi) on 24 May 1996. Professor of Medicine (Hematology and Oncology) at University of Freiburg (Germany) on 16 March 2005.

Professional Summary

- Board-certified Internist, Hematologist and Oncologist with full academic credentials and 10 years of clinical experience (hematology, hematologic malignancies, transplant, solid tumors).

- Strong experience and skillset in preclinical and clinical drug development in hematology and oncology, with 15 years of industry experience, study phases 1 through 4, global filings, regulatory approvals, medical affairs

- Strategic mindset with excellent leadership and communication skills.

Professional Experience

Senior VP, Global Head, Clinical Hematology/Oncology March 2014 – today

Genentech Inc., A Member of the Roche Group, South San Francisco, CA, USA

Global Therapeutic Area Head, Product Development, with responsibility for Hematology and Oncology portfolio. Reporting to Chief Medical Officer.

VP, Global Clinical Development, Oncology November 2011 – March 2014

Genentech Inc., A Member of the Roche Group, South San Francisco, CA, USA

Responsible for Clinical Development of HER Signaling Franchise in Oncology. Focus on registrational trials, including pre-launch and marketed drugs. First global approvals of Perjeta® (Pertuzumab) and Kadcyla® (trastuzumab emtansine) in metastatic breast cancer, line extensions for Herceptin® (trastuzumab) and Perjeta®. Leading Oncology team in US and Europe. Reporting to SVP Global Clinical Development Oncology.

VP, TA Head, Global Clinical Development, Oncology October 2009 – November 2011

Bayer Healthcare Pharmaceuticals Inc., Montville, NJ, USA

Global Therapeutic Area Head with portfolio management responsibility for Oncology Global Clinical Development. Focus on registrational trials for mid and late stage Oncology therapeutics, including pre-launch and marketed drugs. Successful label-enabling phase 3 trials for Stivarga® (regorafenib, CRC and GIST), Xofigo® (Alpharadin, prostate cancer) and Nexavar® (thyroid cancer). Leading Oncology team in US, Europe and Asia. Reporting to SVP Global Clinical Development.

Executive Director, Early Development, Oncology December 2007 – October 2009

Amgen Inc., Thousand Oaks, California, USA

Global program responsibility for Early Development (Medical Sciences) Oncology, including several first in human and phase 1b programs in Oncology Therapeutics. Reporting to VP Medical Sciences.

Executive Director, Global Clinical Development, Oncology October 2006 – October 2009

Amgen Inc., Thousand Oaks, California, USA

Global program responsibility for Clinical Development of Oncology drugs, including two phase 3 programs. FDA and EMA approval of Kepivance® (palifermin) in hematopoietic stem cell transplant. Approval of Nplate® (romiplostim, for ITP) in US, Europe, Switzerland, Australia, Canada, and Japan. Reporting to VP Global Clinical Development Hematology/Oncology.

Director, Global Clinical Development, Oncology April 2005 – September 2006

Amgen Inc., Thousand Oaks, California, USA

Global program responsibility for Clinical Development of Kepivance® (palifermin) including Phase I-III program in different indications. Reporting to VP Hematology/Oncology, Global Clinical Development. Chair of Global Product Strategy Team. Clinical Development trial activities (Phase I-III).

Therapeutic Area Head, Oncology September 2003 – April 2005

Amgen Europe AG, Lucerne, Switzerland

Leading Oncology TA in Europe, with teams on European level as well as in 25 European countries. Reporting to Vice President MA Europe. Member of European Leadership Team. Co-Chair of European Business Team Oncology. Medical Communication, Phase II-IV trials.

Medical Director, Head of Medical Department February 1999 – August 2003

Amgen GmbH, Munich, Germany

Leading Clinical Development, Drug Safety and Regulatory Affairs, Medical Information, and Medical Affairs. Reporting to Country Manager. Member of German Executive Management Team. Holder of general commercial power of attorney ("Prokurist"). Qualified person according to German law for

Drug Safety and Clinical Development. Clinical Development (Phase I-III) and Medical Affairs (Phase IIIB-IV) programs in Hematology/Oncology, Immunology/Rheumatology and Nephrology.

Instructor, Internal Medicine and Hematology/Oncology October 1998 – February 1999

University of Freiburg Medical Hospital. Focus on hematologic malignancies and solid tumors. Head of the Clinical Research/GCP Center of the University of Freiburg Medical Hospital.

Research Physician January 1997 – September 1998

Scripps Research Institute, La Jolla, CA, USA

Immunology of T cells and dendritic cells. Adoptive transfer as basis for immunologic therapeutic approaches for viral and malignant diseases. Peptide vaccination and DNA vaccination.

Instructor, Internal Medicine and Hematology/Oncology April 1995 – December 1996

University of Freiburg Medical Hospital. Associate Professor and Lecturer in Hematology and Oncology April 1996. Focus on hematologic malignancies, stem cell transplant and solid tumors.

Head, Clinical Research/GCP-Center July 1993 – December 1996

University of Freiburg Medical Hospital. Focus on development and implementation of clinical studies in Hematology and Oncology (academic and industry-sponsored clinical trials).

Resident and Fellow, Internal Medicine / Hematology / Oncology December 1989 – March 1995

University of Freiburg Medical Hospital. Focus on internal medicine, emergency medicine, nephrology, rheumatology/immunology and hematology/oncology. Clinical and epidemiological studies of hereditary tumors (Von Hippel-Lindau disease, Multiple Endocrine Neoplasia).

Oncotest Laboratories GmbH May 1988 – November 1989

Head of Preclinical Drug Development Group. In vitro and in vivo assays of drug efficacy. Development of tumor models for targeted therapies. Regulation of proliferation and angiogenesis in solid human tumors, with focus on polypeptide growth factors / angiogenesis factors and their receptors. Close collaboration with NCI, EORTC, CRC and NDDO.

Professional Society Memberships

- American Society of Hematology (ASH)

- American Society of Clinical Oncology (ASCO)

- American Association of Cancer Research (AACR)

- German Society of Hematology and Oncology (DGHO)

- German Cancer Society (DKG)

Awards and Grants

- “Studienstiftung des Deutschen Volkes” (German People’s Study Foundation), 1985 – 1988.

- “Deutsche Forschungsgemeinschaft” (German Research Association), 1997 – 1998.

- Research Award of Albert Ludwigs University, Freiburg, for doctoral thesis, 1989.

- Research Award of the German Cancer Society, for experimental work on angiogenesis, 1995.

Biographical Information

- Born 13 May 1962, German citizen
- Married to J.E. Maneiro Romero (Spanish), two children (Sarah, *2001, David, *1996)
- Languages: German (native speaker), English (fluent), Spanish (intermediate)

(last updated 25.09.2017)