JULIE KROP, MD

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SUMMARY

Innovative, strategic **physician executive** with a breadth of executive leadership experience across multiple therapeutic and orphan indications in the biopharmaceutical industry including pre-commercial and commercial organizations. Member of the FDA Pulmonary/Allergy Drugs Advisory Committee

KEY COMPETENCIES

- Demonstrated track record of success in the design and timely execution of clinical trials for biologics, small molecules, drug-device combinations, and gene therapy resulting in multiple drug approvals in the US and EU.
- Extensive experience in early and late-stage development of both orphan and non-orphan drug candidates through approval and post-approval life cycle management including support of commercial launches.
- Strong regulatory background resulting in successful pre-IND meetings, EOP2 meetings, US and EMEA filings and FDA and EMEA advisory panels.
- Unique combination of strong technical skills with a strategic, practical, and entrepreneurial focus on successfully driving companies to meet their strategic objectives

PROFESSIONAL EXPERIENCE

Aquestive Therapeutics (NASDAQ AQST) 2021 – Present
Board of Directors- Chair, Science and Technology Committee

Beth Israel Deaconess Cancer Center 2023 – Present
Advisory Board

Profound Research CRO 2024- Present
Scientific Advisory Board Member

PureTech Health*, Boston, MA* 2021 – 2024
Chief Medical Officer and Head of Development

- Leadership, management, and oversight of research and drug development.
- Key presenter at investor conferences and external presentations.
- Key decision maker and participant in internal and external due diligenc for potential business partners.
- Built, cultivated, and led a fully integrated Development organization with multiple cross functional teams including Translational Medicine, Clinical Development, Regulatory Affairs, Medical Affairs, Pharmacovigilance, CMC, Program Management, and Clinical Operations for multiple clinical-stage programs.
    - Transitioned and led multiple rare disease pre-clinical candidate from pre-clinical development through phase 1 and early POC. Designed and led successful phase 2b IPF registration enabling study, Phase 2a AML and Head and Neck I/O study, and multiple early-stage studies (2 Phase 1 and 3 pre-clinical) evaluating a novel drug delivery platform.

Freeline Therapeutics, Stevenage, England 2020 – 2021
Chief Medical Officer

- Key contributer to successful IPO 8/2020 raising over $200m.
- Built and led a highly functioning integrated development organization consisting of Clinical, Regulatory, Medical Affairs, PV, and Clinical Operations.
- Launched and built out US headquarters.
- Designed and oversaw 3 clinical Stage gene therapy programs.

AMAG Pharmaceuticals, Waltham, MA 2015 – 2020
Chief Medical Officer, Executive Vice President, Development
Chief Medical Officer, SVP, Clinical Development & Regulatory Affairs

- Sourced, hired, and built a Development organization (70+) consisting of clinical development, regulatory affairs, clinical operations, program management, statistics, medical writing, medical affairs, and pharmacovigilance. Involved in 3 commercial launches.
- Key spokesperson — media, investor relations, advocacy.

Regulatory/Clinical Development Accomplishments at AMAG:

- Created and built Development and Medical Affairs functions from 6 people to 70+ that achieved multiple FDA approvals
  - Designed and successfully executed 2,000 patient CV outcome trial leading to sNDA approval of Fereheme for iron deficiency anemia with and without CKD
  - sNDA approval of Makena SC Autoinjector, orphan drug to reduce the rate of pre-term birth in women with a prior pre-term birth.
  - NDA approval of Vylessi, a novel MC4 agonist for treatment of hyposexual desire disorder.
  - Ciraparantag, obtained fast track status for the reversal of factor Xa inhibitors in a patient with a severe bleed or requiring urgent surgery- asset phase 2b ready.
  - DIF, orphan drug for treatment of severe pre-eclampsia in phase 2b/3a.
  - Key presenter and moderator for FDA Advisory committee meeting.

Vertex Pharmaceuticals, Boston, MA 2012 – 2015
Vice President, Clinical Development ***(2014 – 2015)***

- Oversight of all early and late-stage development programs for all non-CF programs in the company.
- Designed and led successful POC for VX-150, a novel pain program currently in phase 3 registration trials
- Developed and led Spinal cord injury program for novel therapeutic.
- Partnered with the Research group to build development plans for all early-stage compounds in the portfolio.
- Introduced and facilitated clinical evaluation of all external business development assets under consideration.

Development Team Lead for Infectious Disease and HCV Franchise, VP, Clinical Development ***(*2012 – 2014)**

- Leadership and strategic direction for all aspects of development (clinical, regulatory, CMC, toxicology, medical affairs) within the Infectious Disease area.
- Collaborated with Commercial Lead to develop strategy for all aspects of the business franchise.
- Primary liaison for all external partnerships in infectious desease
- Led all clinical development teams related to infectious desease
- Orchestrated all post-marketing strategies and post-approval commitment studies.
- Evaluated and was key decision maker in external business development opportunities for the franchise.

Stryker Regenerative Medicine, Hopkinton, MA **2006-2012**
Vice-President, Clinical Development and Regulatory Affairs

- Played key role in developing overall strategic business plan for the division.
- Led development strategy for all Clinical and Regulatory activities; assisted in preclinical efficacy and safety studies, IND preparation, clinical trial design and protocol development, management of conduct of trials, and regulatory strategy and execution for product approvals.
- Obtained EMEA approval of BMP-7 for spinal fusion surgery and led FDA Advisory Panel Meeting for approval in US.
- Successfully advanced drug candidates from IND through a phase 2 proof of concept study in osteoarthritis and degenerative disk disease.

Peptimmune, Cambridge, MA 2003 – 2006

Vice-President of Clinical Development

- Led clinical development and clinical operations for the company.
  - Phase 1 and phase 2 clinical studies in obesity, MS, and pemphigus vulgaris (orphan drug designation).
- Key participant in Raising capital for the company as well as business development discussions with potential large pharmaceutical partners.

Millennium Pharmaceuticals, Cambridge, MA 2001 – 2003
Senior Director, Clinical Research for Metabolic Diseases and Inflammation

- Led pre-clinical and early clinical programs for Millennium/Abbott metabolic collaboration.
- Designed and completed successful Phase 2b proof of concept study evaluating MLN-02 for ulcerative colitis and Crohn's Disease that was ultimately approved by FDA and is a multibillion dollar blockbuster. (Entyvio).
- Co-led committee to establish processes to improve quality for the development organization including improving clinical trial data collection and analysis.

Pfizer Pharmaceuticals, Central Research, Groton, CT 1999 – 2001
Associate Director, Clinical Research

Johns Hopkins University School of Medicine, Baltimore, MD
Instructor, Faculty member, Department of Medicine, Division of Endocrinology

EDUCATION

Brown University, 8-Year Program in Liberal Medical Education, BA with honors.

Brown University School of Medicine, MD. Graduated with high honors.

Georgetown University Hospital, Resident, Department of Medicine.

Johns Hopkins School of Medicine, Fellow, Department of Endocrinology.

Robert Wood Johnson Clinical Scholars Program, Johns Hopkins University School of Medicine. Selective two-year fellowship in epidemiology and clinical trial design, execution, and statistical analysis.

Harvard Business School Executive Management Program

Academic Honors

- ✓ *American College of Physicians Scholarship for Internal Medicine*
- ✓ *American Medical Women's Association- Janet Glasgow memorial Achievement award for academic Excellence*
- ✓ *Society of Sigma Xi*

ACADEMIC EXPERIENCE

Johns Hopkins School of Medicine, Department of Endocrinology
Curriculum development and teaching of core curriculum in endocrinology for house staff and medical students.

Johns Hopkins University School of Medicine
Group leader for diabetes section of medical school pathophysiology course.

Johns Hopkins School of Medicine Admissions Committee
Member of Medical School Admissions- Johns Hopkins School of Medicine.

BOARD CERTIFICATION/PROFESSIONAL COMMITTEES

Diplomate, American Board of Internal Medicine, Board certified in Endocrinology
Member of Endocrine Society
Member Healthcare Businesswomen's Association

Steering Committee, Boston CMO Network
Co- Chair and Moderator for 6th and 7th Annual Chief Medical Officer Summit, May 2018/April 2019
HBA invited speaker "Navigating a Path to the C-Suite" June 2018 Speaker
Member of HBA executive Woman's Forum in Boston
Selected to participate in Executive Woman in Bio's Boardroom Ready Program

PUBLICATIONS

Kingsberg SA, Clayton AH, Portman D, Williams LA, Krop J, Jordan R, Lucas J, Simon JA. Bremelanotide for the Treatment of Hypoactive Sexual Desire Disorder "Two Randomized Phase 3 Trials". Obstet Gynecol. 2019;134:899-908

Simon JA, Kingsberg SA, Portman D, Williams LA, Krop J, Jordan R, Lucas J, Clayton AH. Long-Term Safety and Efficacy of Bremelanotide for Hypoactive Sexual Desire Disorder. Obstet Gynecol 2019;134:909-917
Kingsberg SA, Schaffir J, Faught BM, Pinkerton JV, Parish SJ, Iglesia CB, Gudeman J, Krop J, Simon JA. Female Sexual Health: Barriers to Optimal outcomes and a Roadmap for Improved Patient-Clinician Communications. J Womens Health (Larchmt). 2019

Wolf M, Chertow GM, Macdougall IC, Kaper R, Krop J, Strauss W. Randomized trial of intravenous iron-induced hypophosphatemia. JCI Insight. 2018 Dec 6;3(23)

Strauss WE, Franklin Adkinson N, Macdougall IC, Auerbach M, Kaper RF, Chertow GM, Krop JS. "A comment on the comparative safety of intravenous ferumoxytol versus ferric carboxymaltose in iron deficiency anemia. Am J Hematol. 2018 Sep;93(9):E232-E233

Adkinson, NF, Strauss WE, Macdougall IC, Bernard KE, Auerbach M, Kaper RF, Chertow GM, Krop JS. Comparative safety of intravenous ferumoxytol vs ferric carboxymaltose in iron deficiency anemia: A randomized trial. Am J Hematol. 2018 May;93(5):683-690

Adkinson, NF,Strauss WE, Bernard K, Kaper RF, Macdougall IC, Krop JS. Comparative safety of intravenous Ferumoxytol versus Ferric Carboxymaltose for the Treatment of Iron Deficiency Anemia: rationale and study design of a randomized double-blind study with a focus on acute hypersensitivity reactions. J Blood Med. 2017 Sep 26;8:155-163

J Krop, w. Kramer. Comparative Bioavailability of Hydroxyprogresterone Caproate administered via Intramuscular injection or subcutaneous autoinjector in healthy postmenopausal women: A Randomized, parallel group, open label study. Clin Ther. 2017 Dec;39(12):2345-2354

Vaccaro AR, Lawrence JP, Patel , Katz LD, Anderson DD, Fishgrund JS, Krop J, Fehlings MG, Wong, D. The Safety and Efficacy of OP-1 (rhBMP-7) as a Replacement for Iliac Crest Autograft in Posterolateral Lumbar Arthrodesis: a Long-Term (>4 years) Pivotal Study. *Spine* 33 (26) 2850-62, Dec 15, 2008.

Bertoni AG. Anderson GF. Krop JS. Brancati FL. Diabetes – Related Morbidity and Mortality in a National Sample of US Elders. [Article] *Diabetes Care.* 25(3): 471-475, 2002 Mar.

Krop JS, Weller W, Shaffer T, Saudek C, Anderson G. "Predicting Expenditures for Medicare beneficiaries with

Diabetes: A Prospective Cohort Study from 1994-1996, *"Diabetes Care* 22: 1660-6, Oct. 1999.

Krop, JS., Coresh, J, Brancati, F. "Black/White Differences in the Incidence of Early Renal Function Decline Among a Community Sample of Diabetes Adults: The Atherosclerosis in Communities (ARIC) Study, " *Archives of Internal Medicine* 159: 1777-83, August 1999.

Krop JS, Weller W, Shaffer T, Saudek C, Anderson G. "Patterns of Expenditures and Use of Services Among Older Adults with Diabetes: Implications for the Transition to Capitated Managed Care", *Diabetes Care* 21: 747-752, May 1998.

Swartzman J. (Krop) and Molloy M., "The Context for Reform" in *Physician Payment Review Commission, Annual Report to Congress*, Washington, DC, 1989.

Editor for *The Johns Hopkins Complete Home Encyclopedia of Drugs*, Medletter Associates, New York, 1998.

ABSTRACTS/ PRESENTATIONS/MANUSCRIPTS

S. Kingsberg, a. Al-Khateeb, S. Karkare, N. Hadker, M. Lim-Watson, J. Krop, L. Williams. Systematic Review of HSDD and ED. *Current Medical Research & Opinion 2019*

J. Simon, S Kingsberg, D. Portman, L, Williams, J. Krop, R. Jordan, J. Lucas, A. Clayton. Long term Safety and Efficacy of Bremelanotide for Hypoactive Sexual Desire Disorder. *Obstetrics & Gynecology (Nov 2019)*

S. Kingberg, A. Clayton, D. Portman, L. Williams, J. Krop, R. Jordan, J. Lucas, J. Simon. Bremelanotide for the Treatment of Hypoactive Sexual Desire Disorder: Two Randomized Phase 3 Trials. *Obstetrics & Gynecology (Nov 2019)*

J. Simon, A. Clyaton, S. Kingsberg, D. Portman, R. Jordan, Lucas, L. Williams, J. Krop. Effect Size of Bremelanotide Treatment in the Phase 3 RECONNECT studies. *NPWH, SMSNA 2019*

S. Kingsberg, A. Clayton, D. Portman, R. Jordan, Revicki, L. Williams, J Krop. Bremelanotide Treatment Provided Clinically meaning Benefits in Premenopausal Women with Hypoactive Sexual Desire Disorder. *NPWH, SMSNA, 2019*

A. Clayton, S. Kingsberg, J. Simon, Lucas, R, Jordan Spana, l. Williams, J. Krop . Safety and Efficacy of bremelanotide in the RECONNECT Studies. *AASECT 2019*

A. Clayton, J. Simon, S ingsberg, R. Jordan, Lucas, L. Williams, J. Krop. Bremelanotide for Hypoactive Sexual Desire Disorder: Contraceptive Subgroups Efficacy Analysis. *ASCP, AAFP 2019*

S. Kingsberg, A. Clayton, J. Simon, R. Jordan, Lucas, L. Williams, J. Krop. Bremelanotide for Hypoactive Sexual Desire Disorder in the RECONNECT Studies: Analysis of Baseline Arousal Subgroups. *SSTAR, AWH 2019*

J. Simon, A. Clayton, S. Kingsberg, R, Jordan, L. Williams, J. Krop. Efficacy of Bremelanotide Across Hypoactive Sexual Desire Disorder Duration Subgroups *ACOG 2019*

A. Clayton, S. Kingsberg, J. Simon, R. Jordan, L. Williams, J. Krop. Bremelanotide for Hypoactive Sexual Desire Disorder: Contraceptive Subgroups Efficacy Analysis *ACOG, AWAH, SMSN, A2019*

A. Clayton, J. Simon, S. Kingsberg, R. Jordan, Lucas, L. Williams, J. Krop. Bremelanotide for Hypoactive Sexual Desire Disorder in the RECONNECT Studies: Analysis of Baseline Free Testosterone Level Quartile Subgroups. *ISSWSH, ASCP 2019*

A. Clayton, J. Simon, S. Kingsberg, R. Jordan, Lucas, L. Williams, J. Krop. Bremelanotide for Hypoactive Sexual Desire Disorder in the RECONNECT Studies: Analysis of Co-Primary Endpoints According to Baseline FSFI Total Scores. *SMSNA 2018*

K. Spadt, Faught, R. Jordon, Lucas, L, Williams, J. Krop. Women's Experiences With Bremelanotide Administered Via Autoinjector, As Desired, for the treatment of Hypoactive
Sexual Desire Disorder. *NPWH 2018*

William E. Strauss,Naomi V. Dahl. John Jiang, Kristine Bernard, Robert F. Kaper, Julie Krop. IV iron treatment of iron deficiency anaemia with Ferumoxytol in patients with inflammatory bowel disease unable to take oral iron: a randomized controlled trial versus ferric carboxymaltose.

Auerbach M, Strauss WE, Macdougall IC, Bernard K, Kaper RF, Chertow GM, Li Z, Trochanov A, Dahl NV, and Krop J. Randomized, Double-Blind Trial of Ferumoxtol compared to Ferric Carboxmaltose for treatment of iron deficiency anemia: safety and efficacy.

Presentation on "The Utility of Administrative Databases for Outcomes Research in Diabetes Mellitus". International Conference on Outcomes Research Applied to Diabetes, January 1998 Berlin, Germany.

Krop JS, Powe NR, Weller W, Shaffer T, Saudek CD, Anderson GF. "Factors Explaining Expenditures and Utilization of Health Care Services Among Medicare Beneficiaries with Diabetes – Implications for Capitation. Presented at CDC Diabetes Translation Meeting in Ft. Lauderdale, April 1998.

Krop JS, Anderson GF, Shaffer T, Brancati. "Preventive Health Services and the Risk of Lower Extremity Amputations in Diabetic Elders: A Population-based Study". Poster presentation at the June 1998 American Diabetes Association meeting.

Krop, JS., Coresh, J, Brancati, F. "Black/White Differences in the Incidence of Early Renal Function Decline Among a Community Sample of Diabetic Adults: The Atherosclerosis in Communities (ARIC) Study." Oral presentation at the Robert Wood Johnson Clinical Scholars National Meeting, November, 1997. Oral presentation at the June 1998 American Diabetes Association meeting.

A Randomized Controlled Trial of a Humanized 4 7 Antibody in Ulcerative Colitis (UC) Brian Feagan, Gordon Greenberg, Gary Wild, John McDonald, Richard Fedorak, Pierre Pare, Kei Kishimoto, Jose-Carlos Guitterez-Ramos, Julie Krop, Millennium Pharmaceuticals, Inc., Robarts Clinical Trials. Oral presentation at the American Gastroenterolgy Association meeting in Orlando, Florida, May 2003.

Efficacy and Safety of a Humanized 4 7 Antibody in Active Crohn's Disease (CD) Brian G. Feagan, Gordon Greenberg, Gary Wild, John McDonald, Richard Fedorak, Pierre Pare, Kei Kishimoto, Jose-Carlos Guitterez-Ramos, Julie Krop, Millennium Pharmaceuticals, Inc., Robarts Clinical Trials. Oral presentation at the American Gastroenterology Association meeting in Orlando, Florida, May 2003.