CURRICULUM VITAE

Tara Lee Frenkl, MD, MPH

Experienced senior pharmaceutical industry executive and strategic drug developer with broad therapeutic experience across Oncology, Immunology, Urology, and Women's Health.

Highlights

- Senior pharmaceutical industry leader with experience in clinical practice, clinical research, and global drug development. Able to design and execute clinical trials intended for global registration across multiple therapeutic areas.

- Breath of experience across oncology portfolios including pembrolizumab, lenvatinib, olaparib, NY-ESO and NextGen cell and gene therapy assets, niraparib, dostarlimab, belantamab mafodotin, cobolimab (anti-TIM-3), anti-TIGIT, anti-CD96, darolutamide, larotrectinib, radium-223, regorafenib and copanlisib.

- Registration Filing /Approval Experience for drugs and devices including pembrolizumab for multiple lines of bladder cancer, darolutamide for prostate cancer, carbetocin for postpartum hemorrhage after vaginal delivery, and NuvaRing Applicator.

- Wide-ranging global labeling and regulatory experience including agency meetings, benefit risk assessment, risk management plans, safety label updates, variations, and device risk management activities.

- Contributed to ODAC preparation for Merck for the Gardasil indication for boys and men and anal cancer, as well as for Proscar and the Prostate Cancer Prevention Trial

- Extensive experience with industry collaboration for drug development including Janssen, Zai Lab, Merck-Serono, SeaGen, Takeda, and iTEOs.

- Proven leadership and management skills with passion for developing others.

- Excellent communications, organizational, and presentation skills.

EDUCATION:

1992	Rutgers University College of Pharmacy New Brunswick, NJ	B.S., Pharmacy Salutatorian Class President 1989-92 Phi Lambda Sigma Phi Eta Sigma Rho Chi Society
1996	Rutgers-Robert Wood Johnson Medical School	M.D. Alpha Omega Alpha
2001	Rutgers University, School of Public Health	M.P.H.

CLINICAL AND RESEARCH TRAINING:

1996-1997	Duke Medical Center Durham, NC	Intern Dept. of Family Practice
1997-1998	Duke Clinical Research Institute Durham, NC	Research Coordinator Cardiology Trial
1998-2003	The Warren Alpert Medical School of Brown University Providence, RI	Resident Dept. of Surgery, Div. of Urology
2003-2005	The Cleveland Clinic Cleveland, OH	Fellow Female Pelvic Medicine and Reconstructive Surgery

POSITIONS:

2022-current	Senior Vice President Head of Oncology Development Oncology Strategic Business Unit Bayer Pharmaceuticals Whippany, NJ
2021-2022	Senior Vice President, Head of Medicine Development Leaders, Oncology GlaxoSmithKline Collegeville, PA
2019-2021	Vice President Medicine Development Lead, Niraparib New Indications beyond Ovarian Cancer Oncology GlaxoSmithKline Collegeville, PA
2016-2019	Executive Director Product Development Team Lead, Pembrolizumab Clinical Oncology, Bladder Cancer Merck Research Labs Merck & Co., Inc. Upper Gwynedd, PA
2014-2016	Executive Director Therapeutic Area Section Head of Women's Health Merck Research Labs Merck & Co., Inc. Upper Gwynedd, PA
2010-2014	Senior Principal Scientist Director of Clinical Research Women's Health 2013-14 Respiratory and Immunology 2010-2013 Merck Research Labs Merck & Co., Inc. Upper Gwynedd, PA
2006-2010	Associate Director Clinical Research Immunology, Analgesia, Anemia and Urology

	Merck Research Labs Merck & Co., Inc. Upper Gwynedd, PA
2008-2022	Adjunct Clinical Staff Division of Urology Hospital of the University of Pennsylvania Philadelphia, PA
2005-2006	Assistant Professor Division of Urology UMDNJ, Robert Wood Johnson Medical School New Brunswick, NJ

BOARD CERTIFICATIONS:

1996	National Board of Medical Examiners
2007	American Board of Urology
2017	Recertification, American Board of Urology

LEADERSHIP DEVELOPMENT PROGRAMS

Nomination based participation in innovative leadership development programs created in partnership between Merck and external education institutions.

Harvard Business School	Merck Emerging Leader Program	2016
Harvard Business School	Merck Build the Best Teams and Talent	2016
Merck Learning and Dev	MRL Business Acumen Program	2016
Wharton School	Merck Executive Leadership Program	2015
Merck Women's Sponsorship Program	Sponsor- Peter Paris Stein	2015-16
Harvard Business Publishing	Leaders Connect	2013-14
Simmons School of Management	Merck Women's Leadership Program	2012
Rutgers University	Mini-MBA BioPharma Innovations Program	2011

PHARMACEUTICAL EXPERIENCE:

Clinical Trials

Associate to Senior Director of Clinical Research (2006-2014)

1. A Phase 2b, Randomized, Double-blind, Placebo-controlled, Dose ranging study of Serlopitant in Patients with Overactive Bladder (MK-0594-003, 2006 -2007)
2. A Phase 1 Randomized, Placebo Controlled, Crossover Study to Evaluate the Effects of Tolterodine Tartrate on Urodynamic Parameters in Patients with Overactive Bladder (MK-0000-107, 2008-2009)
3. A Phase 3, Double-Blind, Placebo-Controlled, Multicenter Trial to Study the Efficacy and Tolerability of MK0663/Etoricoxib in the Treatment of Pain After Abdominal Hysterectomy (MK-0663-097, 2008-2010)
4. A Phase IIb Randomized, Placebo- and Active Comparator (Tolterodine)-Controlled, 2-Part Clinical Study of the Efficacy and Safety of MK-4618(vibegron) in Patients with Overactive Bladder (MK-4618-008a, 2011-2012)
5. A 52-week Extension to: A Phase IIb Randomized, Placebo- and Active Comparator (Tolterodine)-Controlled, 2-Part Clinical Study of the Efficacy and Safety of MK-4618 (vibegron) in Patients with Overactive Bladder (MK-4618-008b, 2011-2013)
6. A Phase 3 Multicenter, Randomized, Double-blind, Placebo-controlled Study of the Effect of Golimumab Administered Subcutaneously in Subjects with Active Axial Spondyloarthritis (MK-8259-006-02, 2012-2014)

Section Head of Women's Health, Clinical Development (2014-2016)

7. A Phase 2 Randomized, Placebo-controlled Clinical Trial to Evaluate the Effect of Contraceptive Vaginal Rings on Primary Dysmenorrhea (P08257/MK-8175A/MK-8342B-057, 2012-2017)
8. A Phase 3, Randomized Double Blind Study Efficacy and Safety of Etonogestrel + 17β-Estradiol Vaginal Ring (MK-8342B) in Women with Primary Dysmenorrhea (With Optional Extension) (MK-8342B-059, 2016-2016)
9. A Phase 3, Randomized Double Blind Study of the Efficacy and Safety of Etonogestrel + 17β-Estradiol Vaginal Ring (MK-8342B) in the Treatment of Women with Primary Dysmenorrhea (MK-8342B-060, 2016-2016)
10. A Phase 3 Single Arm Trial of Efficacy and Safety of Etonogestrel + 17β-

Estradiol Vaginal Ring in Women at Risk for Pregnancy (MK-8342B-061, 2015-2016)

11. A Phase 3, Randomized, Active-Comparator Controlled Clinical Trial to Study the Contraceptive Efficacy and Safety of the MK-8342B (Etonogestrel + 17β-Estradiol) Vaginal Ring and the Levonorgestrel-Ethinyl Estradiol (LNG-EE) 150/30 μg Combined Oral Contraceptive (COC) in Women at Risk for Pregnancy ((MK-8342B-062, 2015-2016)
12. A Multicenter, Open Label, Randomized, Two-period Crossover Study on the Insertion of MK-8342A (NuvaRing®) Placebo with and without the Use of NuvaRing Applicator in Healthy Female Subjects ((MK-8342A-063, 2014-2015)
13. A Phase 3, Randomized, Placebo-Controlled Study of Heat-Stable Carbetocin versus Oxytocin to Prevent Hemorrhage after Vaginal Birth (CHAMPION Study with World Health Organization, 2015-2018)

<u>Product and Clinical Development Lead (Pembrolizumab, Bladder Cancer 2016-2019)</u>

14. A Phase 3 Study of Pembrolizumab (MK-3475) Versus Paclitaxel, Docetaxel, or Vinflunine for Participants with Advanced Urothelial Cancer (KEYNOTE-045, 2014-2017)
15. A Phase 2 Study of Pembrolizumab (MK-3475) in Participants with Advanced Urothelial Cancer (KEYNOTE-052, 2015-2019)
16. A Phase 2 Study of Pembrolizumab (MK-3475) and Pembrolizumab in Participants with High Risk Non-muscle Invasive Bladder Cancer (KEYNOTE-057) (2014-2019)
17. A Phase 3 Randomized, Double-Blind Trial Study of Pembrolizumab with or Without Platinum-based Combination Chemotherapy Versus Chemotherapy Alone in Urothelial Carcinoma (KEYNOTE-361, 2C016-2021)
18. A Phase 3 Randomized, Double-Blind Trial of Pembrolizumab (MK-3475) in Combination with Epacadostat (INCB024360) or Placebo in Participants with Cisplatin-ineligible Urothelial Carcinoma (KEYNOTE-672/ECHO-307, 2017-2018)
19. A Phase 3 Randomized Double-Blind Trial Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with Bacillus Calmette-Guerin (BCG) in High-Risk Non-Muscle Invasive Bladder Cancer (HR NMIBC) (KEYNOTE-676, 2018)
20. A Phase 3 Randomized, Double-Blind Perioperative Pembrolizumab (MK-3475) Plus Cystectomy Plus Cystectomy Versus Cystectomy Alone in Participants Who Are Cisplatin-ineligible or Decline Cisplatin with Muscle-

invasive Bladder Cancer (KEYNOTE-905, 2018)

21. A Phase 3 Randomized, Double-Blind Perioperative Pembrolizumab (MK-3475) Plus Neoadjuvant Chemotherapy Versus Perioperative Placebo Plus Neoadjuvant Chemotherapy for Cisplatin-eligible Muscle-invasive Bladder Cancer (MIBC) (KEYNOTE-866, 2019)
22. A Phase 3 Randomized, Double-Blind Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with Chemoradiotherapy (CRT) Versus CRT Alone in Muscle-invasive Bladder Cancer (MIBC) (KEYNOTE-992, 2020)

Product and Clinical Development Lead (Niraparib, 2019-2021)

23. Efficacy and Safety Comparison of Niraparib to Placebo in Participants with Human Epidermal Growth Factor 2 Negative (HER2-) Breast Cancer Susceptibility Gene Mutation (BRCAmut) or Triple-Negative Breast Cancer (TNBC) With Molecular Disease (positive ctDNA) (ZEST, 2021)
24. A Phase III, Randomized, Placebo-controlled Study Comparing Niraparib Plus Pembrolizumab Versus Placebo Plus Pembrolizumab as Maintenance Therapy in Participants with Advanced/Metastatic Non-small Cell Lung Cancer (ZEAL-1L, 2020)
25. A Phase 1, Multicenter, Open-label, Dose Escalation and Cohort Expansion Study of Niraparib and Dostarlimab in Pediatric Participants with Solid Tumors (SCOOP, 2020)

Registration Filing/Approval Experience (Select)

1. Global Approval including US, EU, China, Japan, plus other countries (RTOR, Project Orbis): Darolutamide in combination with docetaxel for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC). (2022-2023, Head of Oncology Development)
2. EU Renewal 2023-2024 for larotrectinib for treatment of adult and pediatric patients with solid tumors that display a Neurotrophic Tyrosine Receptor Kinase (NTRK) gene fusion (2023, Head of Oncology Development)
3. US Approval: Pembrolizumab for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy. (2020, Clinical and Product Development Team Lead- completed submission package)
4. US Accelerated Approval: Pembrolizumab for the treatment of patients with locally advanced or mUC who were not eligible for cisplatin-containing chemotherapy as determined by an FDA-approved test, or in patients who

were not eligible for any platinum-containing chemotherapy regardless of PD-L1 status 2017, revised based on new data in 2018 to patients whose tumors expressed PD-L1 (Combined Positive Score [CPS] ≥10), (2017-2018, Clinical and Product Development Team Lead)

5. Global "conditional" and full approvals including EU, Canada, Australia and multiple other countries: Pembrolizumab for the treatment of locally advanced or metastatic urothelial carcinoma in adults who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 with a combined positive score (CPS) ≥10 (2017-2019, Clinical and Product Development Team Lead)
6. Global Approval including US, EU, Japan, Australia, and other countries: Keytruda as monotherapy is indicated for the treatment of locally advanced or metastatic urothelial carcinoma in adults who have received prior platinum-containing chemotherapy (2017-2019, Clinical and Product Development Team Lead)
7. Swissmedic Approval: Heat-stable carbetocin for the prevention of post-partum hemorrhage – the first medicine approved under the Swissmedic and Marketing Authorization for Global Health Products (MAGHP) procedure which aims to build capacity and speed up access to essential medicines in low- and middle-income countries. (2019, Merck for Mothers Scientific Consultant)
8. US Approval: NuvaRing Applicator, 2016 (Clinical and Product Development Team Lead)
9. EU CE Mark: NuvaRing Applicator. 2016 (Clinical and Product Development Team Lead)

Health Authority Experience (Select)

1. Clinical lead for multiple FDA EOP2 and EMA Scientific Advice Meetings
    - Niraparib plus Pembrolizumab as Maintenance Therapy in Advanced/ Metastatic Non-small Cell Lung Cancer
    - Niraparib for HER2- Breast Cancer BRCAmut or Triple-Negative Breast Cancer (TNBC) With Molecular Disease (positive ctDNA)
    - Pembrolizumab in Combination with Bacillus Calmette-Guerin (BCG) for High-Risk Non-Muscle Invasive Bladder Cancer (HR NMIBC)
    - Pembrolizumab for Muscle Invasive Bladder Cancer Studies
    - Etonogestrel + 17β-Estradiol Vaginal Ring (MK-8342B, Next Generation Vaginal Ring) for Indications of Contraception and Dysmenorrhea
    - MK-4618 (Vibegron) for Overactive Bladder
    - NuvaRing Applicator for vaginal ring insertion

2. FDA SEALD Meeting
    - Bladder Diary PRO as primary endpoint in overactive bladder studies
    - Novel Pain PRO as primary endpoint for dysmenorrhea

studies for Next Generation Vaginal Ring

3. FDA pre-sBLA meeting
    - Pembrolizumab in High Risk Non-muscle Invasive Bladder Cancer
4. FDA Voluntary Withdrawal
    - ALIQOPA NDA Withdrawal and Opening of Expanded Access Program
5. FDA Break Through Designation
    - mHER2 EGFR inhibitor (BAY 2927088) for NSCLC
6. Health Canada Consultations
    - MK-4618 (Vibegron) for overactive bladder
    - MK-8432-B (Next Generation Vaginal Ring) for indications of Contraception and Dysmenorrhea
    - Pembrolizumab in Combination with Bacillus Calmette-Guerin (BCG) in High-Risk Non-Muscle Invasive Bladder Cancer (HR NMIBC)
7. PMDA Consultations
    - Pembrolizumab for Locally Advanced or Metastatic Urothelial Carcinoma in Adults Who Have Received Prior Platinum-containing Chemotherapy
    - EOP2 for Vibegron for Overactive Bladder

Pharma and Leadership Experience (Select)

- As Head of Oncology Development at Bayer
    - Responsible for directing Development activities for Bayer's Oncology portfolio and for key Development functions including Regulatory Affairs, Data Analytics and Statistical Sciences, Clinical Operations, and Project Management for all Oncology, and Clinical Development for late-stage Oncology
        - Current Bayer marketed portfolio: NUBEQA® (darolutamide); XOFIFO® (Radium 223); VITRAKVI® (larotrectinib), STIVARGA® (regorafenib); ALIQOPA® (copanlisib). Early pipeline focused on targeted radiotherapy, immuno-oncology and precision medicine candidates
    - Corporate Governance Responsibilities:
        - Member of Pharmaceutical Global Leadership Council
        - Co-Chair Oncology Sounding Board – technical and scientific review of medicine and clinical development plans
        - Voting member, One Oncology Committee- approval of clinical phase advancement of new candidates
        - Voting Member, Global Safety and Labeling Committee
        - Voting Member, Research Portfolio Review Committee
    - Created the "Development Forum" for all of Bayer Oncology Development

to enable adoption of emerging regulatory science trends, clinical and statistical topics that are novel and relevant to global cancer drug development; topics have included Project Optimus, Clinical Trial Diversity and Artificial intelligence/Machine Learning applications in drug development, and Patent Reported Outcomes in oncology.

- As Head of Medicine Development Leaders, Oncology at GSK
    - Member of GSK Development Review Committee (technical and scientific review of medicine and clinical development plans) and Portfolio Investment Board
    - Accountable for Oncology Portfolio Prioritization which included NY-ESO and NextGen Cell and Gene Therapy assets, ZEJULA®, JEMPERLI®, BLENREP®, cobolimab (anti-TIM-3), anti-TIGIT, and anti-CD96
    - Joint Steering Committee and Co-Chair Roles across GSK partnerships including Takeda, Zai Lab, Janssen, iTeos and Merck Serono
    - Member of multiple internal Steering Committees for improvement initiatives across GSK
        - Digital Data and Technology Acceleration
        - Accelerating Submissions
        - Oncology People and Culture Pillar (Chair)
        - Simplification
        - Development Quality Council

- As a Director of Clinical Research at Merck
    - Co-Led the Product Development Team (PDT) Leader Effectiveness Planning Team (2018-2019) which led the continuous education of all PDT leaders across Merck Research Labs to align process, build leadership, and teach an onboarding course for new PDT leaders.
    - Provided clinical and regulatory advice for the CHAMPION study which was an unprecedented collaboration of Merck for Mothers with the World Health Organization and Ferring Pharmaceuticals to conduct a 30,000-woman global study conducted in developing countries as the basis for heat-stable carbetocin (a uterotonic) to prevent post-partum hemorrhage, and subsequently make it accessible to developing countries to reduce maternal mortality worldwide.
        - Results of the study were published in NEJM and were the basis for the inclusion of carbetocin in the WHO guidelines, and filing (sNDA) submitted to Swiss Medic in April 2019 with approval May 2020.

- Clinical Research Representative on Merck PRO Committee (2013-2019)
  - Responsible for strategizing, advising and approving the use of patient reported outcomes (PRO) used in Phase 2 and 3 programs across all therapeutic areas at Merck

- Participated in Merck preparation for 3 FDA Advisory Committee Meetings
  - Gardasil indication for boys and men (2009) and anal cancer (2010)
  - Proscar and Prostate Cancer Prevention Trial (2010)

- As Adjunct Clinical Staff, Division of Urology Hospital of the University of Pennsylvania
  - Maintained a clinical practice ~ 2 days/month (no personal payment received)

ACADEMIC AND PROFESSIONAL HONORS:

2020	**GSK Transformational Medicine Award –** Niraparib NSCLC Study
2018	**Merck PDT Leaders Award** for Build the Best Teams
2018	**Merck INSIPRE Awards** for Foster Collaboration, Rapid Disciplined Decision Making
2017	**Merck INSPIRE Awards** for Heroics during Cyberattack, and MRL Divisional Pipeline
2016	**Merck Rahway Team Award** for Collaboration
2014	**Merck First in Man for Novel Compound**
2014	**Merck Leadership in Clinical Development & Execution, Vibegron out-licensing**
2007-2009	**Merck and Co, Inc – 3 Performance based Awards of Excellence**
2006	**Early Career Women Faculty Professional Development Seminar**, Competitive entry seminar, co-sponsored by the American Academy of Medical Colleges and Harvard Medical School, July 8-11, 2006
2003	**Pfizer Scholars in Urology Award** for Leadership, Innovation, and Outstanding Achievement in Urologic Science during Residency.
1996	**Janet M. Glasgow Memorial Achievement Citation**, Recognition by the American Medical Women's Association of women who graduate in the top ten percent of their class or are considered honor graduates
1996	**Alpha Omega Alpha**, National Medical **Honor** Society
1992	**Geriatric Summer Fellowship**, New Brunswick, New Jersey
1992,1991	**Phi Lambda Sigma**, National Pharmacy Leadership Society
1992	**Phi Eta Sigma**, National Collegiate Honor Society
1992	**Herbert-Remmner Award**, given by Pharmacology/Toxicology Department for academic excellence and leadership
1992	**Graduation Speaker**, Pharmacy Class of 1992, Elected by faculty and peers
1991	**Merck- AFPE Gateway Scholar**, Grant awarded to 4 undergraduate students in the US per year to support a promising research proposal in the pharma sciences

1991-92	**Rho Chi Society**, National Colleges of Pharmacy Honor Society
1989-92	**Rutgers College of Pharmacy Research Honors Program**
1987-92	**New Jersey Distinguished Scholar**, Annual academic scholarship
1987-88	**Montclair Women's League College Scholarship,** Academic scholarship

MEMBERSHIPS:

2017-present	American Society of Clinical Oncology
2017-present	European Society of Clinical Oncology
1998-present	American Urology Association

MANUSCRIPTS

1. *KEYNOTE-057: open-label, multicentre, phase 2 study of pembrolizumab monotherapy for the treatment of high-risk non–muscle invasive bladder cancer unresponsive to bacillus Calmette-Guérin*. Balar A, Kamat A, Kulkarni GS, Uchio EM, Boormans JL, Roumiguié M, Krieger L, Singer EA, Bajorin BF, Grivas P, Seo KY, Nishiyama H, Konety BR, Li H, Nam K, Kapadia E, **Frenkl T**, de Wit R. Lancet Oncology 021; 22: 919-30.

2. *Long-Term Outcomes in KEYNOTE-052: Phase 2 Study Investigating First-Line Pembrolizumab in Cisplatin- Ineligible Patients With Locally Advanced or Metastatic Urothelial Cancer*. Vuky, J, Balar A, Castellano D, O'Donnell PH, Grivas, P, Bellmunt J, Powles, T, Bajorin D, Hahn N, Savage M, Fang X, Godwin, JL, **Frenkl, T**, Moreno BH, de Wit, R, Plimack E. Journal of Clinical Oncology; 38(23) 2020.

3. *The Cost Effectiveness of Pembrolizumab versus Chemotherapy or Atezolizumab as Second-Line Therapy for Advanced Urothelial Carcinoma in the United States*. Slater RL, Lai Y, Zhong Y, Li H, Meng Y, Moreno BH, Godwin JL, **Frenkl TL**, Sonpavde, GP, Mamtani R. J Med Econ. 2020; 23(9): 967-77.

4. *Pembrolizumab as First-Line Therapy in Cisplatin-Ineligible Advanced Urothelial Cancer(KEYNOTE-052): Outcomes in Older Patients by Age and Performance Status*. Grivas, Plimack E, Balar A, Castellano D, O'Donnell PH, Bellmunt J, Powles, T, Hahn N, de Wit, R, Bajorin D, Ellison MC, **Frenkl TL**, Godwin, JL, Vuky J. European Urology Oncology 2020. 3: 351-7.

5. *KEYNOTE-676: Phase III study of BCG and pembrolizumab for persistent/recurrent high-risk NMIBC.* Kamat A, Shore N, Hahn N, Alanee S, Nishiyama H, Shariat S, Nam K, Kapadia E, **Frenkl T,** Steinberg G. Future Oncology 2020. 16 (10): 507–16.

6. *Pembrolizumab versus chemotherapy in recurrent, advanced urothelial cancer*

in Japanese patients: a subgroup analysis of the phase 3 KEYNOTE-045 trial. Nishiyama H, Yamamoto Y, Sassa N, Nishimura K, Fujimoto K, Fukasawa S, Yokoyama M, Enokida H, Takahashi K, Tanaka Y, Imai K, Shimamoto T, Perini R, **Frenkl T**, Bajorin D, Bellmunt J. Int J Clin Oncol 2020 25(1):165-74.

7. *Systematic Literature Review and Meta-Analysis of Response to First-Line Therapies for Advanced/Metastatic Urothelial Cancer Patients Who Are Cisplatin Ineligible*. Freshwater T, Li, Valiathan C, Li M, Perini R, Bracco OL, **Frenkl T,** Keefe S. American Journal of Clinical Oncology: Cancer Clinical Trials 2019 42(10): 802-9.

8. *Randomized phase III KEYNOTE-045 trial of pembrolizumab versus paclitaxel, docetaxel, or vinflunine in recurrent advanced urothelial cancer: Results of >2 years of follow-up.* Fradet Y, Bellmunt J., Vaughn DJ, Lee JL, Fong L, Vogelzang NJ, Climent MA, Petrylak DP, Choueiri TK, Necchi A, Gerritsen W, Gurney H, Quinn DI, Culine S, Sternberg CN, Nam K, **Frenkl TL**, Perini RF, De Wit R, Bajorin DF. Annals of Oncology 2019 30 (6): 970-6.

9. *Vibegron (RVT-901/MK-4618/KRP-114V) Administered Once-Daily as Monotherapy or Concomitantly With Tolterodine in Patients with an Overactive Bladder: A Multicenter, Phase IIb, Randomized, Double-blind, Controlled Trial Efficacy and Safety of Vibegron in Patients With Overactive Bladder.* Mitcheson D, Samanta S, Muldowney K, Pinto CA, Rocha B, Green S, **Frenkl TL**. European Urology 2019 75(2): 274-82.

10. *A phase 2b multicenter, randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy and safety of vaginal rings containing nomegestrol acetate or etonogestrel and 17β-estradiol in the treatment of women with primary dysmenorrhea*. Fox M.C., Klipping C., Nguyen A.M., **Frenkl TL,** Cruz S.M., Wang Y., Korver T. Contraception 2019 99 (2): 125-130.

11. *Phase II dose-finding study on ovulation inhibition and cycle control associated with the use of contraceptive vaginal rings containing 17β-estradiol and the progestagens etonogestrel or nomegestrol acetate compared to NuvaRing*. Duijkers I, Klipping C, Heger-Mahn D, Fayad GN, **Frenkl TL**, Cruz SM, Korver T. European Journal of Contraception and Reproductive Health Care 2018 23(4): 245-54.

12. *Pharmacological Characterization of a Novel Beta3 Adrenergic Agonist, Vibegron: Evaluation of Anti- Muscarinic Receptor Selectivity for Optimal Combination Therapy for Overactive Bladder.* Di Salvo J, Nagabukuro H, Wickham A, Stickins D, Abbadie C, DeMartino JA, Fitzmaurice A, Gichuru L, Kulick A, Donnelly ML, Jochnowitz N, Pereira A, Sanfiz A, Veronin G, Villa K, Woods J, Zamlynny B, **Frenkl TL**, Zycband e, Edmondson S, and Struthers M. Journal of Pharmacology and Experimental Therapeutics 2017. 360(2):346- 55.

13. *Safety and efficacy of the NuvaRing® Applicator in healthy females: A multicenter,*

open-label, randomized, 2- period crossover study. Feldman R, **Frenkl TL**, Yacik C, Wang Y, Fox MC. Contraception 2016; 94: 362-5.

14. *Discovery of Vibegron: A Potent and Selective β3 Adrenergic Receptor Agonist for the Treatment of Overactive Bladder*. Edmondson SD, Zhu C, Kar NF, Di Salvo J, Nagabukuro H, Sacre-Salem B, Dingley K, Berger R, Goble SD, Morriello G, Harper B, Moyes CR, Shen DM, Wang L, Ball R, Fitzmaurice A, **Frenkl T**, Gichuru LN, Ha S, Hurley AL, Jochnowitz N, Levorse D, Mistry S, Miller RR, Ormes J, Salituro GM, Sanfiz A, Stevenson AS, Villa K, Zamlynny B, Green S, Struthers M, Weber AE. J Med Chem 2016 Jan 28;59(2):609-23.

15. *Perioperative use of etoricoxib reduces pain and opioid side-effects after total abdominal hysterectomy: a double-blind, randomized, placebo-controlled phase III study.* Viscusi ER, **Frenkl T,** Hartrick CT, Rawal N, Kehlet H, Papanicolaou D, Gammaitoni A, Ko AT, Morgan LM, Mehta A, Curtis SP, Peloso PM. Curr Med Res Opin 2012. 28(8): 1323-35.

16. *Evaluation of an experimental urodynamic platform to identify treatment effects: A randomized placebo- controlled crossover study in patients with overactive bladder.* **Frenkl T**, Railkar R, Shore N, Bailen J, Sutherland S, Burke J, Ruddy M, Beals C. Neurourology and Urodynamics 2012. 31(1):69-74.

17. *Variability of Urodynamic Parameters in Patients with Overactive Bladder.* **Frenkl T,** Railkar R, Palcza J, Scott B, Alon A, Green S, Schaefer W. Neurourology and Urodynamics 2011. 30:1565–9.

18. *A multicenter, double-blind, randomized, placebo-controlled trial of a neurokinin-1 receptor antagonist for overactive bladder.* **Frenkl T**, Zhu H, Reiss T, Seltzer O, Green S. Journal of Urology 2010. 184(2):616-22.

19. *Bladder Dysfunction in Mice with Experimental Autoimmune Encephalomyelitis.* Cengiz Z, Altuntas L, Daneshgari F, Guiming L, Adebola F, Kavran M, Johnson J, Gulen M, Jaini R, Li X, **Frenkl T**, Tuohy V. Neuroimmunol 2008.15;203(1):58-63.

20. *Management of iatrogenic foreign bodies of the bladder and urethra following female pelvic floor surgery.***Frenkl T**, Vasavada S, Rackley R, Goldman H. Neurourology and Urodynamics 2008. 27(6):491-495.

21. *Sexually Transmitted Infections.* **Frenkl T**, Potts J. Urologic Clinics of North America 2008. 35: 33-46.

22. *Tension Free Midurethral Slings.* Daneshgari, F, **Frenkl T**, AUA Update Series 2006. Vol 26; Lsn 3 American Urologic Association, Inc. Houston, Texas 2007.

23. *Office Based Transurethral Needle Ablation of the Prostate With Analgesia and Local Anesthesia.* Leocádio DE, **Frenkl T,** Stein, BS. Journal of Urology 2007. 178(5):2052-54.

24. *Results of Cystocele Repair: A Comparison of Traditional Anterior Colporrhaphy, Polypropylene Mesh and Porcine Dermis.* Handel LN, **Frenkl T**, Kim YH. Journal of Urology 2007. 178(1): 153-156.

25. *Sexually Transmitted Diseases. Part 1.* **Frenkl T**, Potts J. AUA Update Series 2006. Vol 25; Lsn 2. American Urologic Association, Inc. Houston, Texas 2006.

26. *Sexually Transmitted Diseases. Part 2.* Frenkl T, Potts J. AUA Update Series 2006. Vol 25; Lsn 3. American Urologic Association, Inc. Houston, Texas 2006.

27. *Injectable neuromodulatory agents: botulinum toxin therapy.* **Frenkl TL**, Rackley RR. Urol Clin North Am. 2005 Feb;32(1):89-99.

28. *The promise of therapy for complex voiding dysfunctions.* Rackley R, **Frenkl T**, Abdelmalak J. Botulinum Toxin: Contemporary Urology 2005:39-52.

29. *Pelvic hematoma as a cause of bladder perforation and gross hematuria*. Lane BR, Moy ML, **Frenkl T**, Hijaz A, Daneshgari F. Urology. 2004 Nov;64(5):1030.

30. *Results of a simplified technique for buried penis repair.* **Frenkl T**, Agarwal S, Caldamone AA. Journal of Urology 2004. 171(2 Pt 1):826-8.

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