

**CURRICULUM VITAE****I. PERSONNEL DATA**

**A. Name:** Nicholas A. Kartsonis, M.D.  
**Work Address:** UG 3D-56  
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**II. HIGH-LEVEL SUMMARY**

Over my 16+ years in the pharmaceutical industry, I have been involved in all aspects of clinical development, including protocol development/execution, global development plan strategy/implementation, NDA/WMA submission, regulatory interactions, in-licensing/due diligence efforts, & project/product team leadership. My efforts have spanned Infectious Diseases (ID) development to include small molecules, vaccines, & biologics.

**III. EDUCATION**

<b><u>School</u></b>	<b><u>Date</u></b>	<b><u>Major</u></b>	<b><u>Degree</u></b>
Clinical/Research Fellow, Massachusetts General Hospital/ Brigham & Women's Hospital Infectious Diseases Program, Boston, MA	1997-1999	Infectious Diseases	Infectious Diseases Specialty
Internal Medicine Residency, Massachusetts General Hospital, Boston, MA	1994-1997	Internal Medicine	Internal Medicine Internship/ Residency
Emory University School of Medicine, Atlanta, GA <i>AΩA, Summa Cum Laude</i>	1990-1994	Medicine	Doctor of Medicine
Emory University Atlanta, GA <i>ΦBK, Summa Cum Laude</i>	1986-1990	Biology ( <i>Major</i> ), Classics/Ancient Greek Literature ( <i>Minor</i> )	Bachelor of Science

IV. **MERCK/MERCK RESEARCH LABORATORIES (MRL) EMPLOYMENT HISTORY**

<b><u>Title</u></b>	<b><u>Time Period</u></b>
Vice President, Therapeutic Area Head, Infectious Diseases Clinical Research	October 2016 to present
Associate Vice President, Section Head for Antibacterials (Cubist integration) Section Head for CMV Clinical Research, Infectious Diseases	January 2015 to September 2016
Executive Director, Section Head for Antibacterials & Antifungals Section Head for Non-Hepatology Viruses (HIV & CMV) Clinical Research, Infectious Diseases/Vaccines	December 2012 to December 2014
Executive Director, Section Head for Antibacterials & Antifungals Section Head for HIV Clinical Research, Infectious Diseases	June 2011 to November 2012
Executive Director, Section Head for Antibacterials & Antifungals Clinical Research, Infectious Diseases	February 2010 to June 2011
Executive Director, Clinical Research, Infectious Diseases/Vaccines	July 2009 to February 2010
Senior Director, Clinical Research, Infectious Diseases/Vaccines	January 2006 to June 2009
Director, Clinical Research, Infectious Diseases/Vaccines	June 2002 to December 2005
Associate Director, Clinical Research, Infectious Diseases	February 2000 to June 2002

**V. NON-MERCK EMPLOYMENT HISTORY**

<u>Title</u>	<u>Time Period</u>
Postgraduate Fellow, Partners AIDS Research Center Massachusetts General Hospital-Charlestown, Massachusetts NIH/NIAID K-08 Award Recipient, starting in 1999	1999 – 2000
Infectious Diseases Attending/Patient Consultation Spaulding Rehab Hospital, Boston, MA North Shore Hospital, Salem, MA	1999 – 2000
Research Fellow/Graduate Assistant, Massachusetts General Hospital Staff/Harvard Medical School	1998

**VI. ACADEMIC EXPERIENCE**

<b>Infectious Diseases Fellowship, Mass General Hospital/ Brigham and Women's Hospital Combined Program, Boston, MA</b> Board Certified, Infectious Diseases, November 1999	July 1997 - June 1999
<b>Internship and Residency, Massachusetts General Hospital, Boston, MA</b> <b>Internship &amp; Residency in Categorical Internal Medicine</b> Board Certified, Internal Medicine, August 1997	July 1994 - June 1997
<b>Medical Degree, Emory University School of Medicine, Atlanta, GA</b> Graduated <i>Summa Cum Laude</i> , May 1994 ΑΩΑ Honor Society Major: Biological Sciences; Minor: Ancient Greek Literature Class Co-Valedictorian	Aug 1990 - May 1994
<b>Graduate, Bachelor of Science, Emory University, Atlanta, GA</b> Graduated <i>Suma Cum Laude</i> , May 1990 ΦBK Honor Society Class Salutatorian	Aug 1986 - May 1990

**VII. SOCIETY MEMBERSHIPS**

Member, Mycoses Study Group (MSG)	2000-2016
Member, Infectious Diseases Society of America (IDSA)	1998-2016
Member, American Society of Microbiology (ASM)	2001-2016
Member, Massachusetts Medical Society	1996-2000
Member, American Medical Association (AMA)	1994-1999
Member, American College of Physicians	1994-1999

**VIII. ACADEMIC AND PROFESSIONAL HONORS**Merck Awards & Honors

Recipient of 16 Merck Awards of Excellence	2001-2016
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Medical School Awards & Honors

Co-Valedictorian, Emory University School of Medicine, Class of 1994	1990-1994
AQA Honor Society, Emory University School of Medicine	1993-1994
Robert W. Woodruff Scholarship Recipient, Emory Univ. School of Medicine	1990-1994
Sandoz Award for Clinical Excellence in Medicine	1994
Member, Who's Who Among American Colleges & Universities	1994
Appleton & Lange Academic Award Recipient	1992

College Awards & Honors

Salutatorian, Emory University, Class of 1990	1986-1990
Phi Beta Kappa Honor Society, Emory University	1989-1990
Alpha Epsilon Upsilon Underclassman Honor Society, Emory University	1986-1987
Eta Sigma Phi Classics Honor Society, Emory University	1989-1990
Emory University Faculty Scholarship Recipient, Emory University	1986-1990

**IX. PUBLICATIONS****Peer-Reviewed Manuscripts - Original Research Articles:**

1. Lucasti C, Vasile L, Sandesc D, Venskutonis D, McLeroth P, Brown M, Losada M, Pedley A, **Kartsonis N**, Paschke A. Efficacy and Safety of Relebactam + Imipenem/Cilastatin in Subjects with Complicated Intra-Abdominal Infection: Results from a Phase 2, Dose-ranging Study. *Antimicrobial Agents & Chemotherapy*, 2016; 60 (10): 6234-6243.
2. Talbot GH, Powers JH, Hoffmann SC on behalf of the Biomarkers Consortium of the Foundation for the National Institutes of Health CABP-ABSSSI & HAPB-VABP Project Teams (**Kartsonis N** as contributing member of team). Progress on Developing Outcomes Assessments as Endpoints for Registrational Clinical Trials of Antibacterial Drugs: 2015 Update from the Biomarkers Consortium of the Foundation for the National Institutes of Health. *Clinical Infectious Diseases*, 2016; 62 (5): 603-7.

3. Cornely OA, Duarte RF, Haider S, Chandrasekar, Helfgott D, Lopez-Jiménez J, Candoni A, Raad I, Laverdiere M, Langston A, **Kartsonis N**, Van Iersel M, Connelly N, H Waskin. Phase 3 pharmacokinetics and safety study of posaconazole tablet in patients at risk for invasive fungal infection, *Journal of Antimicrobial Chemotherapy*, 2016; 71: 718-26.
4. Mori M, Imaizumi M, Asami K, Ishiwada N, Kaneko T, Kigasawa H, Goto H, Kato K, Hara J, Kosaka Y, Koike K, Kawamoto H, Maeda N, Yoshinari T, Kishino H, Takahashi K, Kawahara S, **Kartsonis NA**, Komada Y. Safety, efficacy, and pharmacokinetics of caspofungin in Japanese pediatric patients with invasive candidiasis and invasive aspergillosis, *J. Infection Chemotherapy*, 2015; 21 (6): 421-6.
5. Duarte R, Lopez J, Cornel OA, Laverdiere M, Helfgott D, Haider S, Chandrasekar P, Langston A, Perfect J, Ma L, van Isreal M, Connelly N, **Kartsonis N**, & Waskin H. Phase 1b study of new posaconazole tablet for the prevention of invasive fungal infections in high risk patients with neutropenia. *Antimicrobial Agents and Chemotherapy*, 2014; 58 (10): 5758-5765.
6. Maertens J, Cornely OA, Ullmann AJ, Heinz WJ, Krishna G, Patino H, Caceres M, **Kartsonis N**, Waskin H, & Robertson MN. Pharmacokinetics and safety of posaconazole IV in patients for invasive fungal disease: a Phase 1b study. *Antimicrobial Agents and Chemotherapy*, 2014; 58 (7): 3610-3618.
7. Zorman JK, Secore SL, Green T, Tan C, Esser M, Raedler M, Kreiswirth BN, Dwala'Aladine D, **Kartsonis N**, McNeely T, Smugar SS, Anderson A, Arduino JM. Surveillance of Naturally Occurring IgG Antibody Titers to the *Staphylococcus aureus* Protein IsdB. *Human Vaccines and Immunotherapeutics*, 2013; 9 (9): 1857-64.
8. Comisar W, Sun P, Li S, Sable C, Schwartz M, Bi S, Chow J, Ngai A, Winchell G, **Kartsonis N**, Stone J. Caspofungin exposure-response relationships in adult patients with mucosal or invasive candidiasis. *Clinical Pharmacology & Drug Development*, 2013; 3 (1): 43-50
9. Fowler VG, Allen KB, Moreira ED, Moustafa M, Isgro F, Boucher HW, Corey R, Carmeli Y, Betts R, Hartzel JS, **Kartsonis NA**, Guris D, DiNubile MJ, Onorato MT, Sobanjo-ter Meulen A. Efficacy and safety of an investigational *Staphylococcus aureus* vaccine in preventing bacteremia and deep sternal wound infections after cardiothoracic surgery. *Journal of American Medical Association*, 2013; 309 (13):1368-1378.
10. Kohno S, Izumikawa K, Yoshida M, Takesue Y, Oka S, Kamei K, Miyazaki Y, Yoshinari T, Aoyama N, Nagayasu R, Iino T, **Kartsonis NA**, Niki Y. A Double-Blind Comparative Study of the Safety and Efficacy of Caspofungin vs. Micafungin in the Treatment of Candidiasis & Aspergillosis. *European Journal of Clinical Microbiology and Infectious Diseases*, 2013; 32 (3):387-97.
11. Talbot GH, Powers JH, Fleming T, Siuciak JA, Bradley J, Boucher H on behalf of the CABP ABSSSI Project Team (**Kartsonis N** as contributing member of team). Progress on developing endpoints for registrational clinical trials of community-acquired bacterial pneumonia and acute bacterial skin and soft structure infections: Update from the Biomarkers Consortium of the Foundation of the National Institutes of Health. *Clinical Infectious Diseases*, 2012; 55(8):1114-1121.
12. Moustafa M, Ortiz-Butcher C, Buekert J, Galphin C, Barreto-Torrella G, Aronoff G, Hartzel J, Reineke-Brown E, Smugar SS. **Kartsonis NA**, Guris D. The immunogenicity and safety of a novel *Staphylococcus aureus* vaccine (V710) in adults with end-stage renal disease receiving hemodialysis: a Phase IIa study. *Clinical and Vaccine Immunology*, 2012; 19(9):1509-16.

13. Harro CD, Betts RF, Hartzel JS, Onorato MT, Lipka J, Smugar SS, **Kartsonis NA**. The Immunogenicity and Safety of Different Formulations of a novel *Staphylococcus aureus* vaccine (V710): results of two Phase I studies. *Vaccine*, 2012; 30(9):1729-36.
14. Ngai A, Bourque M, Lupinacci R, Strohmaier K, **Kartsonis NA**. Overview of the safety experience with caspofungin in clinical trials conducted over the first 15 years: A brief report, *International Journal of Antimicrobial Agents*, 2011; 38(6):540-4.
15. Ryan D, Lupinacci RJ, **Kartsonis NA**. Efficacy and safety of caspofungin in obese patients. *Medical Mycology*, 2011; 49(7):748-754.
16. Chi-Chung L, Sun P, Dong Y, Bi S, Desai R, Fallon Dockendorf M, **Kartsonis NA**, Ngai AL, Bradshaw S, Stone JA. Population pharmacokinetics and pharmacodynamics of caspofungin in pediatric patients. *Antimicrobial Agents and Chemotherapy*, 2011; 55(5):2098-2105.
17. Harro C, Betts R, Orenstein W, Kwak E-J, Greenberg HE, Padgett L, Onorato MT, Hartzel J, Lipka J, DiNubile MJ, **Kartsonis NA**. Safety and immunogenicity of a novel *Staphylococcus aureus* vaccine: Results from a first-in-man dose-ranging study. *Clinical and Vaccine Immunology*, 2010; 17(12):1868-74.
18. Walsh TJ, Maertens JA, Madero L, Reilly AF, Lehrenbecher T, Groll A, Jafri H, Green M, Nani JJ, Bourque MR, Wise BA, Strohmaier KM, Taylor AH, **Kartsonis NA**, Chow JW, Arndt CA, Depauw BE. Reply editorial response: Caspofungin versus liposomal amphotericin B: Are they really comparable?. *Pediatric Infectious Diseases Journal*, 2010; 29(10):985-6.
19. Colombo AL, Ngai AL, Bourque M, Bradshaw SK, Strohmaier KM, Taylor AF, Lupinacci RJ, **Kartsonis NA**. Caspofungin use in patients with invasive candidiasis caused by non-albicans *Candida species*: Review of the caspofungin database. *Antimicrobial Agents and Chemotherapy*, 2010; 54(5):1864-71.
20. Maertens J, Madero L, Reilly A, Lehrenbecher T, Groll A, Jafri H, Green M, Nania J, Bourque MR, Wise BA, Strohmaier KM, Taylor AF, **Kartsonis NA**, Chow JW, Arndt CAS, dePauw BE, Walsh TJ. A randomized, double-blind, multicenter study of caspofungin vs. liposomal amphotericin B for empirical antifungal therapy in pediatric patients with persistent fever and neutropenia. *Pediatric Infectious Disease Journal*, 2010; 29(5):415-20.
21. Zaoutis T, MD, Lehrenbecher T, Groll AH, Steinbach WJ, Jafri HS, Maertens J, Ngai AL, Chow JW, Taylor AF, Strohmaier KM, Bourque M, Bradshaw SK, Petrecz M, **Kartsonis NA**. Safety experience with caspofungin in pediatric patients. *Pediatric Infectious Disease Journal*, 2009; 28:1-4.
22. Raedler M, Heyne S, Wagner E, Shalkowski S, Secore S, Anderson A, Cook J, Cope L, McNeely T, Retzlaff M, Shanter J, Rubinstein L, Green T, **Kartsonis N**, Esser MT. A serology assay to quantify human IgG antibodies to *Staphylococcus aureus* iron surface determinant B antigen. *Clinical and Vaccine Immunology*, 2009; 16:739-48.
23. Betts R, Nucci MR, Talwar D, Gareca M, Quieroz-Telles F, Bedimo R, Herbrecht R, Ruiz-Palacios G, Young J, Strohmaier KM, Tucker KA, Taylor AF, **Kartsonis NA**. A multicenter, double-blind trial of a high-dose caspofungin regimen versus a standard caspofungin regimen in adult patients with invasive candidiasis. *Clinical Infectious Diseases*, 2009; 48:1676-84.
24. Neely M, Jafri HS, Seibel N, Knapp K, Adamson P, Strohmaier K, Bi S, Bradshaw S, Li X, Stone JA, **Kartsonis NA**. The pharmacokinetics and safety of caspofungin in toddlers and infants (3 to 24 months of age). *Antimicrobial Agents and Chemotherapy*, 2009; 53(4):1450-6.
25. Saez-Llorens X, Macias M, Maiya P, Pineros J, Jafri H, Chatterjee A, Ruiz G, Raghavan J, Bradshaw SK, **Kartsonis NA**, Sun P, Strohmaier, KM, Fallon M, Bi S, Stone JA, Chow JW.

- Pharmacokinetics and safety of caspofungin in neonates and infants less than 3 months of age. *Antimicrobial Agents and Chemotherapy*, 2009; 53:869-75.
26. Zaoutis T, Jafri H, Huang L, Locatelli F, Barzilai A, Ebell W, Steinbach W, Bradley J, Lieberman J, Hsiao C, Seibel N, Laws H, White M, Petrecz M, Taylor A, Strohmaier K, Chow J, **Kartsonis N**, Ngai A. A prospective, multicenter study of caspofungin for the treatment of documented invasive fungal infections in pediatric patients. *Pediatrics*, 2009; 123: 877-884.
  27. Dinubile MJ, Strohmaier KM, Lupinacci RJ, Meihbohm AR, Sable CA, **Kartsonis NA**. Efficacy and safety of caspofungin therapy in elderly patients with proven or suspected invasive fungal infections. *European Journal of Clinical Microbiology & Infectious Diseases*; 2008; 27: 663-670.
  28. Petrovic J, Ngai A, Bradshaw S, Williams-Diaz A, Taylor A, Sable A, Vuocolo S, **Kartsonis N**. Efficacy and safety of caspofungin in solid organ transplant recipients. *Transplant Proceedings*, 2007; 39 (10):3117-20.
  29. Cornely OA, Lasso M, Betts R, Klimko N, Vazquez J, Dobb G, Velez J, Williams-Diaz A, Lipka J, Taylor A, Sable C, **Kartsonis N**. Caspofungin for treatment of less common forms of invasive candidiasis. *Journal of Antimicrobial Chemotherapy*, 2007; 60:363-9.
  30. Sobel JD, Bradshaw SK, Lipka CJ, **Kartsonis NA**. Caspofungin in the treatment of symptomatic candiduria. *Clinical Infectious Diseases*, 2007; 44:e46-9.
  31. Maertens J, Glasmacher A, Herbrecht R, Aoun M, Thiebault A, Cordonnier C, Segal BH, Caillot D, Sable C, Killar J, Taylor A, **Kartsonis N**, and Patterson TF. Multicenter, Noncomparative Study of Caspofungin in combination with other antifungals in adults with invasive aspergillosis. *Cancer*, 2006; 107:2888-97.
  32. Dinubile M, Lupinacci R, Strohmaier K, Sable C, **Kartsonis N**. Invasive candidiasis in the ICU: observations from a randomized clinical trial. *Journal of Critical Care*, 2007; 22 (3):237-244.
  33. Betts R, Glasmacher A, Maertens J, Maschmeyer G, Vazquez J, Teppler H, Taylor A, Lupinacci R, Sable C, and **Kartsonis NA**. Efficacy of caspofungin against invasive *Candida* or invasive *Aspergillus* infections in neutropenic patients. *Cancer*, 2006; 106:466-73.
  34. Walsh TJ, Adamson PC, Seibel NL, Flynn PM, Neely MN, Schwartz C, Shad A, Kaplan S, Roden MM, Stone JA, Miller A, Bradshaw SK, Li SX, Sable CA, and **Kartsonis NA**. An open-label, sequential dose-escalation study to investigate the pharmacokinetics, safety, and tolerability of caspofungin in children and adolescents. *Antimicrobial Agents and Chemotherapy*, 2005; 49:4536-45.
  35. **Kartsonis N**, Bartizal K, Motyl M, Killar J, Mixson L, Hoe C-M, and Sable CA. Caspofungin Susceptibility Testing of Isolates from Patients with Esophageal Candidiasis or Invasive Candidiasis: Relationship of MIC to Treatment Outcome. *Antimicrobial Agents and Chemotherapy*, 2005; 49 (9):3616-23.
  36. DiNubile MJ, Hille D, Sable CA, and **Kartsonis NA**. Invasive candidiasis in cancer patients: observations from a randomized clinical trial. *Journal of Infection*, 2005; 50 (5): 443-9..
  37. Maertens J, Glasmacher A, Selleslag D, Ngai A, Ryan D, Layton M, Taylor A, Sable C, and **Kartsonis N**. Evaluation of serum sandwich enzyme-linked immunosorbent assay for circulating galactomannan during caspofungin therapy: results from the caspofungin invasive aspergillosis study. *Clinical Infectious Diseases*, 2005; 41:e9-14.
  38. **Kartsonis NA**, Saah A, Lipka CJ, Taylor A, and Sable CA. Salvage Therapy with Caspofungin for Invasive Aspergillosis: Results from the Caspofungin Compassionate Use Study. *Journal of Infection*, 2005; 50 (3): 196-205.

39. Marr KA, Hachem R, Papanicolaou G, Somani J, Arduino JM, Lipka CJ, Ngai AL, **Kartsonis NA**, Chodakewitz J, and Sable C. Retrospective study of the hepatic safety profile of patients concomitantly treated with caspofungin and cyclosporin A. *Transplant Infectious Diseases*, 2004; 6: 110-116.
40. Maertens J, Raad I, Petrikos G, Boogaerts M, Selleslag D, Petersen FB, Sable CA, **Kartsonis NA**, Ngai A, Taylor A, Patterson TF, Denning DW, and Walsh TJ for the Caspofungin Salvage Aspergillosis Study Group. Efficacy and safety of caspofungin for treatment of invasive aspergillosis in patients refractory to or intolerant of conventional antifungal therapy. *Clinical Infectious Diseases*, 2004; 39: 1563-71.
41. **Kartsonis NA**, Saah A, Lipka CJ, Taylor A, and Sable CA. Second-line Therapy with Caspofungin for Mucosal or Invasive Candidiasis: Results from the Caspofungin Compassionate Use Study. *Journal of Antimicrobial Chemotherapy*, 2004; 53: 878-81.
42. Colombo AL, Perfect J, DiNubile M, Bartizal K, Motyl M, Hicks P, Lupinacci R, Sable C, **Kartsonis N**. Global distribution and outcomes for *Candida* species causing invasive candidiasis: results from an international randomized double-blind study of caspofungin versus amphotericin B for the treatment of invasive candidiasis. *European Journal of Clinical Microbiology & Infectious Diseases* 2003; 22:470-4.
43. **NA Kartsonis** and J Perfect. Caspofungin versus amphotericin B for invasive candidiasis (letter). *New England Journal of Medicine*, 2003; 348 (13); 1287-8.
44. Mora-Duarte J, Betts R, Rotstein C, Colombo AL, Thompson-Moya L, Smietana J, Lupinacci R, Sable C, **Kartsonis N**, Perfect J. Comparison of caspofungin and amphotericin B for invasive candidiasis. *New England Journal of Medicine*. 2002; 347:2020-9.
45. Villanueva A, Gotuzzo E, Arathoon E, Noriega, LM, **Kartsonis N**, Lupinacci R, Smietana J, DiNubile MJ, Sable CA. A randomized double-blind study of caspofungin vs. fluconazole for treatment of esophageal candidiasis. *American Journal of Medicine* 2002; 113:294-9.
46. **Kartsonis N**, DiNubile MJ, Bartizal K, Hicks PS, Ryan D, Sable CA. Efficacy of caspofungin in the treatment of esophageal candidiasis resistant to fluconazole. *JAIDS*. 2002; 31:183-7.
47. Martinez-Picado J, DePasquale MP, **Kartsonis N**, et al. Antiretroviral resistance during successful therapy of HIV type 1 infection. *Proceedings of the National Academy of Sciences of the United States of America*. Sept 2000; 97 (20):10948-53.
48. O'Neal JP, **Kartsonis NA**, et al. The Role of protein phosphorylation in the regulation of the Na-K-2C1 cotransport by cell volume in aortic endothelial cells. *Journal of the American Society of Nephrology*. December 1991; 2 (3):747.
49. Evans BD, Pohl J, **Kartsonis NA**, and RL Calabrese. The identification of FMRF-amide as a neuropeptide in the medicinal leech. *Peptides*. September 1991; 12 (1): 897-908.

**Accepted/Submitted Abstracts – Oral Presentations or Posters of Original Research:**

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3. McLeroth P, Akers W, Brown M, Lee Y-C, Du, J, Pedley A, **Kartsonis N**, Paschke A. Phase 2 Study of Relebactam (REL) + Imipenem/Cilastatin (IMI) vs IMI Alone in Subjects with Complicated Urinary Tract Infection (cUTI). Accepted as a poster presentation at the 1<sup>st</sup> American Society of Microbiology (ASM) Microbe meeting, Boston, Massachusetts, June 2016.
4. Goldstein EJC, Citron DM, Gerding DN, Wilcox MH, Tipping R, Dorr MB, Gabryelski L, Eves K, **Kartsonis N**, Pedley A. Recurrent *Clostridium difficile* Infection (rCDI) & Colonization in the 12 Months following Administration of Actoxumab (ACT) & Bezlotoxumab (BEZ). Accepted as a poster presentation (Poster #448) at the 1<sup>st</sup> American Society of Microbiology (ASM) Microbe meeting, Boston, Massachusetts, June 2016.
5. Goldstein EJC, Citron DM, Gerding DN, Wilcox MH, Tipping R, Dorr MB, Gabryelski L, Eves K, **Kartsonis N**, Pedley A. Recurrent *Clostridium Difficile* Infection and Colonization in the 12 Months Following Administration of Actoxumab and Bezlotoxumab. Accepted as an encore presentation at the Anaerobe Congress, Nashville, Tennessee, July 2016.
6. Wilcox MH, Rahav G, Dubberke E, Gabryelski L, Tipping R, Guris D, **Kartsonis N**, Dorr MB. Impact of *C. difficile* infection (CDI) diagnostic method on assessment of bezlotoxumab efficacy for prevention of recurrence. Accepted as an encore presentation at the Anaerobe Congress, Nashville, Tennessee, July 2016.
7. Kelly CP, Gerding DN, Rahav G, Lee C, Dubberke E, Kumar P, Eves K, Pedley A, Tipping R, Guris D, **Kartsonis N**, Dorr MB. The monoclonal antibody, bezlotoxumab targeting *C. difficile* toxin B shows efficacy in preventing recurrent *C. difficile* infection (CDI) in patients at high risk of recurrence or of CDI-related adverse outcomes. Accepted as an encore oral presentation (AGA Presidential Plenary) at the Digestive Disease Week 2016, San Diego, California, May 2016.
8. Wilcox MH, Rahav G, Dubberke E, Gabryelski L, Tipping R, Guris D, **Kartsonis N**, Dorr MB. Impact of *C. difficile* infection (CDI) diagnostic method on assessment of bezlotoxumab efficacy for prevention of recurrence. Accepted as a poster presentation at the 25<sup>th</sup> European Conference on Clinical Microbiology and Infectious Diseases, Amsterdam, Netherlands, April 2016.
9. Gerding DN, Kelly C, Rahav G, Lee C, Dubberke E, Kumar P, Eves K, Pedley A, Guris D, **Kartsonis N**, Dorr MB. Efficacy of the monoclonal antibody, bezlotoxumab (bezlo) targeting toxin B for prevention of recurrence in patients at high risk of recurrence or CDI-related adverse outcomes. Accepted as a poster presentation at the 25<sup>th</sup> European Conference on Clinical Microbiology and Infectious Diseases, Amsterdam, Netherlands, April 2016.
10. Lucasti C, Vasile L, Sandesc D, Venskutonis D, McLeroth P, Chen P, Brown M, Losada M, Pedley A, **Kartsonis N**, Paschke A. A Phase 2 Study to Evaluate the Efficacy & Safety of Relebactam (REL) + Imipenem/Cilastatin (IMI) vs IMI Alone in Subjects with Complicated Intra-Abdominal Infection (cIAI). Presentd as a poster presentation (Abstract F-259) at the 55<sup>rd</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), San Diego, CA, September 2015.
11. Wilcox MH, Gerding D, Poxton I, Kelly C, Nathan R, Cornely OA, Rahav G, Lee C, Eves K, Pedley A, Tipping R, Guris D, **Kartsonis N**, Dorr MB. Bezlotoxumab (BEZ) Alone and With Actoxumab (ACT) for Prevention of Recurrent *C. difficile* Infection (rCDI) in Patients on Standard of Care (SoC) Antibiotics: Integrated Results Across 2 Phase 3 Studies (MODIFY I and MODIFY II). Presented as oral presentation at the IDWeek15, San Diego, CA, October 2015.

12. Wilcox M, Gerding D, Poxton I, Kelly C, Nathan R, Rahav G, Cornely O, Jenkin G, Jensen W, Eves K, Pedley A, Tipping R, Guris D, **Kartsonis N**, Dorr MB. Phase 3 Double-Blind Study of Actoxumab (ACT) & Bezlotoxumab (BEZ) for Prevention of Recurrent *C. difficile* Infection (rCDI) in Patients on Standard of Care (SoC) Antibiotics (MODIFY I). Presented as oral presentation at the 55<sup>rd</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), San Diego, CA, September 2015.
13. Gerding D, Wilcox M, Poxton I, Kelly C, Birch T, Bouza E, Lee C, Sun Kim Y, Yoshida J, Gabryelski L, Pedley A, Taylor A, Guris D, **Kartsonis N**, Dorr MB. Phase 3 Double-Blind Study of Bezlotoxumab (BEZ) alone & with Actoxumab (ACT) for Prevention of Recurrent *C. difficile* Infection (rCDI) in Patients on Standard of Care (SoC) Antibiotics (MODIFY II). Presented as oral presentation at the 55<sup>rd</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), San Diego, CA, September 2015.
14. Cornely OA, Haider S, Grigg A, Van Iersel M, Caceres M, Hepler D, Waskin H, **Kartsonis N**, Robertson MN. Phase 3 Pharmacokinetics and Safety Study of Posaconazole IV in Patients at Risk for Invasive Fungal Infection. Presented as oral presentation [Abstract #A-292] at the 53<sup>rd</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Denver, Colorado, September 2013.
15. Arrieta A, Sung L, Berthold F, Groll AH, Lehrnbecher T, Bradley J, Zwaan CM, Li J, Waskin H, Walker M, **Kartsonis N**, Paschke A, Walsh TJ. Safety, Tolerability, and Pharmacokinetics of Posaconazole Oral Suspension in Neutropenic Children. Presented as poster presentation [Abstract #A-456] at the 53<sup>rd</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Denver, Colorado, September 2013.
16. Nassander U, Kersemaekers WM, van Iersel M, Xuan F, Caceres M, **Kartsonis N**, H Waskin. Pharmacokinetics and Safety Study of Posaconazole IV Solution via Peripheral Administration in Healthy Subjects. Presented as poster presentation [Abstract #A-455] at the 53<sup>rd</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Denver, Colorado, September 2013.
17. Fowler VG, Allen KB, Moriera E, Moustafa M, Isgro F, Boucher H, Corey R, Carmeli Y, Betts R, Hartzel JS, McNeely T, **Kartsonis N**, Guris D, Onorato MT, Smugar S, DiNubile M, Sobanjo-ter Meulen A. Efficacy and safety of an investigational *Staphylococcus aureus* vaccine in preventing bacteremia and deep sternal wound infections after cardiothoracic surgery. Presented as oral presentation (Late Breaker Session #180) at the IDWeek12, San Diego, CA, October 2012.
18. Maertens J, Cornely OA, Ullmann AJ, Heinz W, Krishna G, Caceres M, **Kartsonis N**, Waskin H, Paton B, Robertson M. Phase 1B study of the pharmacokinetics and safety of posaconazole IV in patients at risk for invasive fungal infection. Presented as poster presentation (Abstract A-1946a) at the 52<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), San Francisco, CA, September 2012.
19. Arduino JM, Brown E, DiNubile M, Guris D, Hartzel H, **Kartsonis N**, Kaslow D, McNeely T, Onorato M, Retzlaff M, Shanter J, Sobanjo-ter Meulen A, vanRheenan S,. Development of a vaccine for *Staphylococcus aureus*: Lessons learned from the Merck V710 program. Accepted as oral presentation at the 15<sup>th</sup> Staphylococci and Staphylococcal Infections Symposium, Lyon, France, August 2012.
20. Allen KB, Fowler VG, Turnbull BW, Moreira ED, Moustafa M, Isgro F, Boucher HW, Corey R, Carmeli Y, Hartzel JS, **Kartsonis NA**, Guris D, Smugar SS, Onorato MT, Sobanjo-ter Meulen A. The efficacy and safety of V710, a *Staphylococcus aureus* vaccine in preventing *S. aureus*

- bacteremia and/or deep sternal wound infections in patients undergoing cardiothoracic surgery. Accepted as oral presentation at the 20<sup>th</sup> European Conference on Clinical Microbiology and Infectious Diseases, London, UK, April 2011.
21. Moustafa M, Ortiz-Butcher C, Buekert J, Galphin C, Barreto-Torrella G, Aronoff G, Hartzel J, Reineke-Brown E, Smugar SS, **Kartsonis NA**, Guris D. The immunogenicity and safety of a novel staphylococcus aureus vaccine (V710) in adults with end-stage renal disease receiving hemodialysis - a Phase IIa study. Presented as poster presentation (Abstract B44) at the National Kidney Foundation Spring Clinical Meetings, Las Vegas, Nevada, April 2011.
  22. Barnard RJ, Adeniji-Adele A, Ramos G, Himmelberger A, Wiedermann RT, Hwang PMT, Quirk EK, **Kartsonis NA.**, Lee A.W., Tipping RW, Miller MD, Hazuda DJ. Longitudinal clonal resistance analysis of treatment-naive patients with chronic hepatitis C (CHC) genotype 1 infection treated with mk-7009, a novel ns3/4a protease inhibitor, in combination with pegylated interferon alfa-2a and ribavirin for 28 days. Presented as a poster presentation at HEPDART 2009, Big Island, Hawaii. December 2009.
  23. Barnard RJ, Adeniji-Adele A, Wiedermann RT, Hwang PMT, Quirk EK, **Kartsonis NA.**, Lee AW, Tipping RW, Miller MD, Hazuda DJ. Longitudinal clonal resistance analysis of treatment-naive patients with chronic hepatitis C (CHC) genotype 1 infection treated with mk-7009, a novel ns3/4a protease inhibitor, in combination with pegylated interferon alfa-2a and ribavirin for 28 days. Presented as a poster presentation at the Antiviral Drug Resistance: Targets And Mechanisms 10th Annual Symposium, Richmond, Virginia, November 2009.
  24. Manns M, Gane E, Rodriguez-Torres M, Stoehr A, Yeh C, Marcellin P, Wiedmann RT Hwang PMT, Barnard RJ, Quirk EK, **Kartsonis NA**, Lee AW. Early viral response (EVR) rates in treatment-naive patients with chronic hepatitis C (CHC) genotype 1 infection treated with MK-7009, a novel NS3/4A protease inhibitor, in combination with pegylated-interferon alfa-2a and ribavirin for 28 days. Presented as oral presentation at the American Association for the Study of Liver Diseases 60th Annual Meeting (AASLD), Boston, Massachusetts, October 2009.
  25. Colombo A, Ngai A, Bourque M, Bradshaw S, Taylor A, Strohmaier K, Lupinacci R, **Kartsonis N.** Caspofungin Efficacy in Invasive Candidiasis due to Non-*albicans Candida* Species. Presented as poster presentation to the 49<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), San Francisco, CA, September 2009.
  26. Ryan D, Lupinacci R, **Kartsonis N.** Efficacy and Safety of Caspofungin in Obese Patients. Presented as poster presentation at the 47<sup>th</sup> Annual Meeting of the Infectious Diseases Society of America (IDSA), Philadelphia, PA, October 2009.
  27. Li C, Sun P, Dong Y, Desai RB, Fallon M, **Kartsonis NA**, Stone JA, Bi S. Population pharmacokinetics and pharmacodynamics of caspofungin in pediatric patients. [Poster Presentation A-006]. Presented at the 48<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy/46<sup>th</sup> Annual Meeting of the Infectious Diseases Society of America, Washington, DC, October 2008.
  28. Betts R., Harro C, Onorato MT, Hartzel J, Lipka CJ, **Kartsonis NA.** Immunogenicity and safety of a novel *Staphylococcus aureus* vaccine (V710) across different age groups. [Poster Presentation G-410]. Presented at the 48<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy/46<sup>th</sup> Annual Meeting of the Infectious Diseases Society of America, Washington, DC, October 2008.
  29. Betts R, Nucci M, Talwar D, Gareca M, Quieroz-Telles F, Bedimo R, Herbrecht R, Ruiz-Palacios G, Young J, Tucker K, Taylor A, **Kartsonis N.** A multicenter, double-blind trial of a

- higher caspofungin dose vs. standard caspofungin dose in patients with invasive candidiasis. [Oral Presentation M-1847]. Presented at the 48<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy/46<sup>th</sup> Annual Meeting of the Infectious Diseases Society of America, Washington, DC, October 2008.
30. Harro C, Betts R, Lipka CJ, Hartzel J, Onorato MT, **Kartsonis NA**. Two phase I studies to investigate the immunogenicity and safety of different formulations of a novel vaccine against staphylococcus aureus (V710) [Poster Presentation - Vaccines Subgroup]. Presented at the 13<sup>th</sup> Staphylococci and Staphylococcal Infections Symposium, Cairns, Australia, September 2008.
  31. Harro C, Betts R, Orenstein W, Kwak E, Greenberg HE, Padget LG, Onorato MT, Hartzel J, Lipka CJ, **Kartsonis NA**. A phase I, dose-ranging study to evaluate the immunogenicity and safety of a novel vaccine against *Staphylococcus aureus* (V710). [Poster Presentation - Vaccines Subgroup]. Presented at the 13<sup>th</sup> Staphylococci and Staphylococcal Infections Symposium, Cairns, Australia, September 2008.
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  33. Zaoutis T, Lehrnbecher T, Groll A, Steinbach W, Jafri H, Maertens J, Ngai AL, Chow JW, Taylor AF, Bourque MR, Bradshaw SK, Petrecz M, **Kartsonis NA**. Safety experience with caspofungin in pediatric patients. [Poster Presentation 4466.4]. Presented at the Pediatric Academic Societies' Annual Meeting, Honolulu, Hawaii, May 2008.
  34. Zaoutis T, Jafri H, Huang L, Locatelli F, Barzilai A, Ebell W, Steinbach W, Bradley J, Lieberman JM, Hsiao C, Seibel NL, Laws H, Petrecz M, Taylor AF, Chow JW, **Kartsonis NA**, Ngai AL. Prospective, multicenter study of caspofungin for treatment of documented fungal infections in paediatric patients. [Poster Presentation]. Presented at the 17<sup>th</sup> European Conference on Clinical Microbiology and Infectious Diseases, Barcelona, Spain, April 2008.
  35. Ostrosky-Zeichner, L, Paetznick VL, Rodriguez J, Chen E, **Kartsonis N**, Douglas C. Activity of caspofungin alone or in combination with amphotericin B lipid complex in a murine model of fusariosis. [Poster Presentation M-1841]. Presented at the 47<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, Illinois, September 2007.
  36. Saez-Llorens X, Macias M, Maiya P, Pineros J, Jafri H, Chatterjee A, Ruiz G, Raghavana D, Bradshaw S, **Kartsonis NA**, Bi S, Sun P, Fallon M, Stone J, Chow JW. Pharmacokinetics and safety of caspofungin in neonates & infants <3 months of age. [Poster Presentation A-773]. Presented at the 47<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, Illinois, September 2007.
  37. Maertens J, Madero L, Reilly A, Lehrnbecher T, Groll A, Jafri H, Green M, Nania J, Bourque MR, Wise BA, Taylor AF, **Kartsonis NA**, Chow JW. A randomized, double-blind, multicenter trial of caspofungin vs. liposomal amphotericin B as empirical antifungal therapy of pediatric patients with persistent fever and neutropenia. [Oral Presentation M-621]. Presented at the 47<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, Illinois, September 2007.
  38. Zaoutis T, Jafri H, Keller N, Huang L, Locatelli F, Barzilai A, Ebell W, Steinbach W, Bradley J, Lieberman JM, Hsiao C, Seibel N, Laws H, Petrecz M, Taylor A, Chow J, **Kartsonis N**, Ngai A. Presented as oral presentation at the 45<sup>rd</sup> Annual Meeting of the Infectious Diseases Society of America, San Diego, California, October 2007.

39. Lyon GM, Adiri Y, Hoover PA, Abramson MA, **Kartsonis NA**. Differences in the epidemiology of invasive candidiasis between academic and community hospitals participating in the *Candida* surveillance study (CASS). [Poster Presentation]. Presented at Society for Healthcare Epidemiology of America 17<sup>th</sup> Annual Scientific Meeting, Baltimore, Maryland, April 2007.
40. Lyon GM, Adiri Y, Abramson MA, Hoover PA, **Kartsonis NA**. The *Candida* surveillance study (CASS): A Second Year Report [Poster Presentation #035]. Presented at FOCUS on Fungal Infections 17, San Diego, California, March 2007.
41. Lyon GM, Sunay S, Karataila S, Adiri YA, Hoover PA, **Kartsonis NA**, Abramson MA. Antifungal susceptibility testing of isolates collected during the first year of the *Candida* Surveillance Study (CaSS). [Poster Presentation #036]. Presented at FOCUS on Fungal Infections 17, San Diego, California, March 2007.
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43. **Kartsonis N**, Teppler H, Bourque M, Williams-Diaz A, Bradshaw S, Taylor A, Isaacs R, Sable C. Efficacy of Caspofungin against Invasive Candidiasis due to 4 Common Non-albicans *Candida* species: Review of the Caspofungin Database. [Poster Presentation #019]. Presented at FOCUS on Fungal Infections 17, San Diego, California, March 2007.
44. **Kartsonis N**, Ngai A, Bradshaw S, Williams-Diaz A, Taylor A, Sable C. Efficacy & Safety of Caspofungin in Solid Organ Transplant Recipients [Poster Presentation]. Presented at the 16<sup>th</sup> European Conference on Clinical Microbiology and Infectious Diseases, Munich, Germany, April 2007.
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49. Maertens J, Glasmacher A, Herbrecht R, Aoun M, Thiebault A, Cordonnier C, Segal BH, Caillot D, Sable C, Ryan D, Taylor A, **Kartsonis N**, and Patterson TF. Multicenter, Noncomparative Study of Caspofungin Combined with Other Antifungals in Adults with Invasive Aspergillosis (IA) Refractory or Intolerant to Prior Therapy: Final Data [Poster Presentation M-954].

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50. **Kartsonis N**, Lipka J, Bradshaw S, Taylor A, Lupinacci R, Sable C. Safety of Caspofungin During Concomitant Immunosuppressant Therapy [Poster Presentation M-759]. Presented at the 45<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Washington, DC, December 2005.
  51. **Kartsonis N**, Teppler H, Dinubile M, Ngai A, Bourque M, Wise BA, Lipka J, Sable C. Safety Experience with Long-term Use of Caspofungin. [Poster P-261]. Presented at the 43<sup>rd</sup> Annual Meeting of the Infectious Diseases Society of America, San Francisco, CA, October 2005.
  52. **Kartsonis N**, Migoya L, DiNubile M, Taylor A, Lupinacci R, Bourque M, Sable C. Overview of Safety Experience with Caspofungin in Clinical Trials. [Poster P-263]. Presented at the 43<sup>rd</sup> Annual Meeting of the Infectious Diseases Society of America, San Francisco, CA, October 2005.
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  55. **Kartsonis NA**, DiNubile M, Meibohm A, Sable C. Safety and tolerability of outpatient caspofungin therapy. [Abstract R-1912]. Presented at 14<sup>th</sup> European Conference on Clinical Microbiology and Infectious Diseases, Prague, Czech Republic, May 2004.
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  59. **Kartsonis NA**, Saah A, Lipka J, Taylor A, Sable C. Salvage Therapy with Caspofungin for Invasive Aspergillosis: Results from the Caspofungin Compassionate Use Study. [Poster M-981]. Presented at the 43<sup>rd</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, Illinois, September 2003.
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  67. DiNubile M, Hille D, Sable C, **Kartsonis N**. Invasive candidiasis in patients with hematologic & solid organ malignancies: results from a randomized, double-blind study of caspofungin vs. amphotericin B. [Abstract 3657]. Presented at the American Society of Hematology, Philadelphia, PA, December 2002.
  68. Mora-Duarte J, Betts R, Rotstein C, Lopes-Colombo A, Thompson-Moya L, Smietana J, Lupinacci R, Sable C, **Kartsonis N** & Perfect J. Caspofungin vs. amphotericin B deoxycholate in the treatment of candidemia: results from a multi-center, randomized, double-blind study. [Oral presentation 13]. Presented at the annual meeting of the Infectious Disease Society of America, Chicago, IL, October 2002.
  69. DiNubile M, Lupinacci R, Sable C, **Kartsonis N**. Central venous catheter management of patients with candidemia. [Poster]. Presented at the annual meeting of the Infectious Disease Society of America, Chicago, IL, October 2002.
  70. Colombo AL, Perfect J, Bartizal K, Motyl, Hicks P. Sable C, DiNubile M, **Kartsonis N**. Geographic distribution & response rates for various *Candida* species: results from the multicenter randomized invasive candidiasis study of caspofungin vs. amphotericin B. [Poster]. Presented at the 42<sup>nd</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, San Diego, CA, September 2002.
  71. Bartizal K, Motyl, Hicks M, Sable C, DiNubile M, **Kartsonis N**. *In vitro* susceptibility results and correlation with outcome: results from the randomized invasive candidiasis study of caspofungin vs. amphotericin B. [Oral presentation]. Presented at the 42<sup>nd</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, San Diego, CA, September 2002.
  72. Walsh TJ, Adamson PC, Seibel NL, Flynn PM, Neely MN, Miller A, Sable CA, **Kartsonis NA**, Stone JA. Pharmacokinetics of caspofungin in pediatric patients. [Poster M-896]. Presented

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  74. Mora-Duarte J, Betts R, Rotstein C, Lopes-Colombo A, Thompson-Moya L, Smietana J, Lupinacci R, Sable C, **Kartsonis N** & Perfect J. Caspofungin vs. Amphotericin B deoxycholate in the Treatment of Invasive Candidiasis in Neutropenic & Non-Neutropenic Patients: A Multi-center, Randomized, Double-Blind Study. [Oral presentation]. Presented at 12<sup>th</sup> European Conference on Clinical Microbiology and Infectious Diseases, Milan, Italy, April 2002.
  75. **Kartsonis NA**, Saah AJ, Lipka CJ, Pohl ER, Sable CA. Results in patients with esophageal, oropharyngeal, or invasive candidiasis from the caspofungin compassionate use study. Presented at FOCUS on Fungal Infections 12, Phoenix, AZ, March 2002.
  76. Villanueva A, Gotuzzo E, Arathoon E, Noriega, LM, **Kartsonis N**, Lupinacci R, Smietana J, Berman RS, DiNubile MJ, Sable, CA. The efficacy, safety, and tolerability of caspofungin vs. fluconazole in the treatment of esophageal candidiasis. Presented at the 41<sup>st</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, IL, December 2001.
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  79. Martinez-Picado J, DePasquale MP, **Kartsonis NA**, Hanna G, et al. Selection of antiretroviral resistance in the latent reservoir of HIV-1 during successful therapy. [Poster 238]. Presented at the 7<sup>th</sup> International Conference on Retroviruses And Opportunistic Infections. San Francisco, CA, January 2000.
  80. De Pasquale MP, **Kartsonis NA**, et al. Selection of protease resistance mutations in semen. [late breaker oral presentation] 6<sup>th</sup> International Conference on Retroviruses And Opportunistic Infections. Chicago IL, January 1999.
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1. **Kartsonis NA**, Nielsen J, Douglas CM. Caspofungin: the first in a new class of antifungal agents. *Drug Resistance Updates*. 2003; 6:197-218.



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