

Craig L. Tandler, M.D.

CURRENT ROLE:

VP, R&D Management (Retired)
Global Head Clinical Development, Diagnostics, and
Med Affairs, Hematology & Oncology,
Johnson & Johnson Innovative Medicine
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EDUCATION:

Undergraduate: 1976-1980, B.A., Biological
Sciences (cum laude), Cornell University
Graduate: 1980-1984, M.D. high honors/AOA,
Mount Sinai School of Medicine

Experience & Key Accomplishments:

- 29 years of drug development and medical affairs (phase I-IV) experience following seven years in academic hematology/oncology
- Therapeutic expertise: Oncology, Hematology, Immunology
- Coordinated/achieved >30 Oncology regulatory approvals and 15 NMEs approved since 2011 (major ones highlighted below):
FDA – RYBREVANT (amivantamab) in combination with lazertinib for the first-line treatment of locally advanced/metastatic non-small cell lung cancer (NSCLC) with common EGFR alterations (Aug. '24), in combination with carboplatin and pemetrexed for the treatment of pts with EGFRm NSCLC whose disease has progressed after an EGFR tyrosine kinase inhibitor (Sep. '24) and in combination with carboplatin and pemetrexed for the first-line treatment of NSCLC with EGFR exon 20 insertion mutation (Mar. '24); **TALVEY** (talquetamab) for treatment of patients with relapsed and refractory multiple myeloma (RRMM) (Aug. '23); **TECVAYLI** (teclistamab) for the treatment of patients with RRMM (Oct. '22); **CARVYKTI** (cilta-cel) for treatment of patients with RRMM who have received at least 1 prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide (Apr. '24); **BALVERSA** (erdafitinib) for metastatic urothelial carcinoma with *FGFR* genetic alterations (Apr '19); **ERLEADA** (apalutamide) for metastatic hormone-sensitive prostate cancer (mHSPC), (Sep '19) and non-metastatic castration resistant prostate cancer (Feb '18); **DARZALEX FASPRO SC** (daratumumab) in combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in patients with newly diagnosed MM who are eligible for transplant (July '24) and in newly diagnosed patients with AL amyloidosis (Jan. '21) and in newly diagnosed or relapsed/refractory multiple myeloma (May '20); **IMBRUVICA** for treatment of frontline CLL (Mar. '16), Waldenström's macroglobulinemia (Jan.'15), and relapsed CLL (Feb.'14); **ZYTIGA** (abiraterone acetate) for mCRPC (chemo refractory/chemo naïve: Apr.'11/Dec'12) and mHSPC (Feb. '18).

EMA - RYBREVANT (amivantamab) in combination with lazertinib for 1st line treatment of advanced NSCLC with common EGFR alterations (Nov. '24) and in combination with chemotherapy for the first-line treatment of advanced NSCLC with EGFR exon 20 insertion mutation (June '24); **TALVEY** (talquetamab) for treatment of patients with RRMM (Aug. '23); **AKEEGA** (niraparib/abiraterone) for patients with mCRPC harboring a BRCA1/2 mutation (Apr.'23); **TECVAYLI** for patients with RRMM (Aug. '22); **CARVYKTI** for patients with RRMM who have received at least three prior therapies (May '22); **ERLEADA** for mHSPC (Jan. '20) and non-metastatic castration resistant prostate cancer (Jan.'19); **DARZALEX FASPRO** for patients with multiple myeloma in all approved daratumumab IV indications (June '20); **IMBRUVICA** for frontline CLL (Apr. '16), Waldenstrom's Macroglobulinemia (July '15), and relapsed CLL/MCL (Oct. '14); **ZYTIGA** for newly diagnosed, mHSPC (Oct. '17) and mCRPC (Sep.'11/Dec.'12)

- Leader/key participant in four Oncology Drug Advisory Committee (ODAC) presentations: DOXIL for breast cancer (July'09), Re-evaluation of PROCRT benefit/risk profile (May'07), TEMODAR post-approval commitment (Mar.'03), INTRON A for non-Hodgkin's lymphoma (Oct.'97)
- Achieved 13 FDA Breakthrough Designations: ibrutinib (4), daratumumab (2), cilta-cel, erdafitinib, amivantamab for Exon 20 Insertion Mutation NSCLC, niraparib for HRR+ mCRPC, teclistamab and talquetamab for RRMM, and TAR-200 for BCG unresponsive for non-muscle invasive bladder cancer
- Lead clinical diligence teams for ~ 30 oncology business development opportunities culminating in Janssen acquisition of Cougar Biotechnology (ZYTIGA) and Aragon (ERLEADA), Janssen co-development deals with Legend Biotech (cilta-cel BCMA CAR-T for multiple myeloma), Pharmacyclics (IMBRUVICA for B-cell malignancies), Yuhan (Lazertinib for EGFRm lung cancer), Geron (Imetelstat for myeloid malignancies), and GenMab (DARZALEX for multiple myeloma)
- Proficient at building highly effective global development and medical affairs teams with disease area focus, working in strategic alignment with commercial teams to deliver differentiated product profiles with strong value propositions
- Skilled at accelerating drug development with strong emphasis on operational excellence, data quality, and risk mitigation by collaborating in an integrated fashion with key internal/external stakeholders to drive rapid and effective decision-making, planning, oversight, and flawless execution
- Proficient at leveraging AI and data sciences in all aspects of clinical trials including study design optimization and site selection to accelerate Oncology drug development
- Experienced in generating matched external control groups with RWE to support early differentiation of novel agents from available therapies, inform development, and facilitate regulatory decision making
- Recognized as a spokesperson for ensuring the company's credibility and trustworthiness with key audiences including patient advocacy groups (played lead role in developing company's policy on pre-approval access and compassionate use), health authorities, payers, and the media

Previous Work Experience at J&J:

- 2010-20: Global Head, Late-Stage Clinical Development and Global Med Affairs
- 2008-10: Vice President, Oncology Global Medical Affairs, Johnson & Johnson and Core Member, Oncology R&D Management Board
- 2006-08: Vice President, Oncology Clinical and Business Development, and Management Board Member, Ortho Biotech (J&J Operating Company)
- 2004-06: Vice President, Clinical Affairs (oncology and virology), and Management Board Member, Tibotec Therapeutics (J&J Operating Company)

Previous Responsibilities:

- Create robust, integrated development plans and data generation activities for all products in the Oncology portfolio, from PoC through registration and lifecycle management, that support new indications, optimize utilization, and provide access for the benefit of patients globally
- Develop and communicate integrated Global Medical Affairs strategies and conduct gap assessments, to ensure regional priorities and data needs are addressed in collaboration with regional medical teams
- Create end-to-end Oncology diagnostic strategies with breadth and scale to unlock the full potential of our biomarker-selected development programs
- Provide Oncology clinical and therapeutic expertise into regional programs, licensing evaluations, and regulatory meetings/submissions
- Develop and execute proactive global publication plans for timely reporting of priority studies in collaboration with R&D and Medical Education teams
- Ensure effective systems are in place for systematically tracking all aspects of study implementation, conduct, and completion in compliance with regulations
- Chair, Oncology Diversity in Clinical Trials Steering Committee, overseeing systematic implementation of diversity plans across the J&J Oncology Portfolio to enhance access to and enrollment of underserved racial/ethnic minorities
- Chair the Clinical/Regulatory Stage Gate Committee to assess and challenge study start-up planning, funding, and resourcing of all oncology clinical development programs
- Drive franchise development through pre-clinical/clinical assessments of in-house and outside development opportunities, including licensing candidates
- Provide clinical input into portfolio management and prioritization exercises to facilitate go/no go decision making
- Primary responsibility for product/protocol safety oversight, acting in the capacity of oncology “franchise safety officer”
- Regularly communicate across our global business units re the status, outcomes, and best practices of key projects within the Oncology portfolio to ensure engagement and alignment around our core strategic objectives
- Attract and develop accountable leaders who motivate others and provide them with development opportunities to ensure their growth and success
- Integrate the Clinical Oncology Teams in China/Japan into Global Development

PREVIOUS PHARMA WORK EXPERIENCE:

- 2001-04: Vice President, Oncology Clinical Research and Chair, Oncology Licensing Committee, Schering-Plough Research Institute
- 2000-01: Sr. Director, Clinical Research, Chair SPRI/Alza Joint Development Team
- 1999-00: Director, Clinical Research, Schering-Plough Research Institute
- 1997-99: Senior Associate Director, Oncology Clinical Research, Schering-Plough Research Institute
- 1995-97: Associate Director, Oncology Clinical Research, Schering-Plough Research Institute, Kenilworth, New Jersey

CLINICAL AND ACADEMIC EXPERIENCE:

- 1992-95: Assistant Professor of Pediatrics and Pediatric Hematology/Oncology, Mount Sinai School of Medicine, New York, New York
- 1991-92: Pediatric Hematology/Oncology Fellow, Mount Sinai Hospital, NY
- 1988-91: Recipient of the Pediatric Scientist Training Program grant, National Cancer Institute, NIH, Bethesda, Maryland
- 1987-88: Pediatric Chief Resident, Mount Sinai Hospital, New York, New York
- 1984-87: Pediatric Intern and Resident, Mount Sinai Hospital, New York, NY

HONORS AND AWARDS:

- 2021: Women of Color in Pharma Trailblazer Award (unwavering commitment to diversity equity and inclusion)
- 2018: J&J Standards of Leadership Award
- 2014: J&J Standards of Leadership Award
- 2009: BIO Innovation Award
- 2004: J&J Standards of Leadership Award
- 1991: Charles Revson Foundation Award
- 1990: Henry Christian Award, American Federation for Clinical Research
- 1988: Pediatrics Physician Scientist Training Award
- 1983: AOA Honor Medical Society (selected as junior; top 5% of class)

LICENSURE/CERTIFICATION:

Licensure: 1991: New Jersey, #56755
1985: New York, #165111

Certification: 1992: Sub-Board Hematology/Oncology
1988: Advanced Cardiac Life Support
1988: American Board of Pediatrics
1985: National Board of Medical Examiners

ACADEMIC/HOSPITAL APPOINTMENTS:

Assistant Professor of Pediatrics (Adjunct), Mount Sinai School of Medicine, 1995-present

COMMITTEES/SOCIETIES/PROFESSIONAL AFFILIATIONS:

2025-present: Scientific Advisory Role for Recursion, TORL BioTherapeutics, nference
2025-present: Special Advisor to the CEO, Compugen
2024-present: Scientific Advisory Board, Ginkgo Bioworks
2023-present: Alternate Industry Representative, Oncology Drug Advisory Committee
2022-present: Co-Chair, Life Sciences Council, CEO Roundtable of Cancer
2022-present: Friends of Cancer Research, Corporate Council (Co-Chair)
2021-present: Bloomberg New Economy International Cancer Coalition
2018-present: MMRF Corporate Council
2017-2022: Admissions Committee, Mount Sinai School of Medicine
2017-present: American Association of Cancer Research
2014-present: ASH Corporate Council
1998: International Society of Interferon and Cytokine Research
1997-present: American Society of Clinical Oncology
1994-present: American Society of Hematology

Publications

1. Melman A, Libin A, **Tendler CL**. The effect of chronic alpha-methyldopa upon sexual function in the adult male rat. *J Urol* 1983; 129:643-5.
2. **Tendler CL**, Bottone EJ. Fusospirochetal ulcerative gingivitis in children. *J. Pediatr* 1987; 111:400-3.
3. **Tendler CL**, Bottone EJ. *Corynebacterium aquaticum*: urinary tract infection in a neonate, and concepts regarding the role of the organism as a neonatal pathogen. *J Clin Microbiol* 1989; 27:343-5.
4. **Tendler CL**, Grossman S, Tenenbaum J. Medication dosages during pediatric emergencies: a simple and comprehensive guide. *Pediatrics* 1989; 84:731-5.
5. Greenberg SJ, **Tendler CL**, Manns A, Bartholomew CF, Hanchard B, Blattner WA, Waldmann TA. Altered cellular gene expression in human retroviral-associated leukemogenesis. In: Blattner W, ed. *Current Issues in Human Retrovirology: HTLV-I*. New York: Raven Press, 1990:87-104.
6. Kim SJ, Kehrl JB, Burton J, **Tendler CL**, Jeang KT, Danielpour D, Thevenin C, Kim KY, Sporn MB, Roberts AB. Transactivation of the transforming growth factor B1 (TGF-B1) gene by human T lymphotropic virus type I tax: a potential mechanism for the increased production of TGF-B1 in adult T-cell leukemia. *J Exp Med* 1990; 172:121-9.
7. **Tendler CL**, Greenberg SJ, Blattner WA, Manns A, Murphy E, Fleisher T, Hanchard B, Morgan O, Burton JD, Nelson DL, Waldmann TA. Transactivation of IL-2 and its receptor induces immune activation in HTLV-I associated myelopathy: pathogenic implications and a rationale for immunotherapy. *Proc Natl Acad Sci USA* 1990; 87: 5218-22.
8. Waldmann TA, Grant A, **Tendler CL**, Greenberg S, Goldman C, Bamford R, Junghans RP, Nelson D. Lymphokine receptor-directed therapy: a model of immune intervention. *J Clin Immunol* 1990; 10:19S-29S.
9. **Tendler CL**, Greenberg SJ, Burton JD, Danielpour D, Kim SJ, Blattner WA, Manns A, Waldmann TA. Cytokine induction in HTLV-I associated myelopathy and adult T-cell leukemia: alternate molecular mechanism underlying retroviral pathogenesis. *J Cell Biochem* 1991;46:302-11.
10. **Tendler CL**, Mandell L, Granowetter L. Local control measures in a toddler with a pelvic primitive neuroectodermal tumor. *Med Pediatr Oncol* 1993; 21:287-94.

11. **Tendler CL**, Burton J, Jaffe J, Danielpour D, Charley M, McCoy JP, Pittelkow M, Waldmann TA. Abnormal cytokine expression in Sézary and adult T-cell leukemia cells correlates with the function diversity between these T-cell malignancies. *Cancer Res* 1994; 54:4430-35.
12. Ozer H, Wiernik PH, Giles F, **Tendler CL**. Recombinant Interferon-therapy in patients with follicular lymphoma. *Cancer* 1998; 82:1821-30.
13. Solal-Celigny P, Lepage E, Brousse N, **Tendler CL**, Brice P, Haioun C, Gabarre J, Pignon B, Tertian G, Bouabdallah R, Rossi, JF, Doyen C, Coiffier B. Doxorubicin-containing regimen with or without interferon alfa-2b for advanced follicular lymphomas: Final analysis of survival and toxicity in the GELF 86 trial. *J Clin Oncol* 1998; 16:233-238
14. Cole BF, Solal-Celigny P, Gelber RD, Lepage E, Gisselbrecht C, Reyes F, Sebban C, Sugano D, **Tendler CL**, Goldhirsch A. Quality-of-life adjusted survival analysis of Interferon alfa-2b treatment for advanced follicular lymphoma: An aid to clinical decision making. *J Clin Oncol* 1998; 16: 2339-44.
15. Srivastava DK, **Tendler CL**, Milani D, English MA, Licht JD, Wilson SH. The HIV-1 transactivator protein tat is a potent inducer of the human DNA repair enzyme β -polymerase. *AIDS* 2001; 15:433-40.
16. Bukowski RM, **Tendler C**, Cutler D, Rose E, Laughlin MM, Statkevich P. Treating cancer with PEG-Intron: pharmacokinetic profile and dosing guidelines for an improved interferon alpha-2b formulation. *Cancer* 2002; 95:389-96.
17. Bukowski R, Ernstoff MS, Gore ME, Nemunaitis JJ, Amato R, Gupta SK, **Tendler CL**. Pegylated interferon alfa-2b treatment for patients with solid tumors: a phase I/II study. *J Clin Oncol* 2002; 20:3841-9.
18. Michallet M, Maloisel F, Delain M, Hellmann A, Rosas A, Silver RT, **Tendler C**, PEG-Intron CML Study Group. Pegylated recombinant interferon alpha-2b vs recombinant interferon alpha-2b for the initial treatment of chronic-phase chronic myelogenous leukemia: a phase III study. *Leukemia* 2004; 18:309-15.
19. O'Brien ME, Wigler N, Inbar M, Rosso R, Grischke E, Santoro A, Catane R, Kieback DG, Tomczak P, Ackland SP, Orlandi F, Mellars L, Alland L, **Tendler C**. Reduced cardiotoxicity and comparable efficacy in a phase III trial of pegylated liposomal doxorubicin HCl (CAELYX/DOXIL) versus conventional doxorubicin for first-line treatment of metastatic breast cancer. *Ann Oncol* 2004; 15:440-9.
20. Khuri FR, Glisson BS, Kim ES, Statkevich P, Thall PF, Meyers ML, Herbst RS, Munden RF, **Tendler C**, Zhu Y, Bangert S, Thompson E, Lu C, Wang X-M, Shin DM, Kies MS, Papadimitrakopoulou V, Fossella FV, Kirschmeier P, Bishop WR, Hong WK. Phase I study of the farnesyltransferase inhibitor lonafarnib with paclitaxel in solid tumors. *Clin Cancer Res* 2004; 10:2968-76.

21. Keller AM, Mennel RG, Georgoulas VA, Nabholtz JM, Erazo A, Lluch A, Vogel CL, Kaufmann M, von Minckwitz G, Henderson IC, Mellars L, Alland L, **Tendler C**. Randomized phase III trial of pegylated liposomal doxorubicin versus vinorelbine or mitomycin C plus vinblastine in women with taxane-refractory advanced breast cancer. *J Clin Oncol* 2004; 22:3893-3901.
22. Jakubowiak AJ, Griffith KA, Reece DE, Hofmeister CC, Lonial S, Zimmerman TM, Campagnaro EL, Schlossman RL, Laubach JP, Raje NS, Anderson T, Mietzel MA, Harvey CK, Wear SM, Barrickman JC, **Tendler CL**, Esseltine DL, Kelley SL, Kaminski MS, Anderson KC, Richardson PG. Lenalidomide, bortezomib, pegylated liposomal doxorubicin, and dexamethasone in newly diagnosed multiple myeloma: a phase 1/2 Multiple Myeloma Research Consortium trial. *Blood*. 2011; 118(3):535-43.
23. Morra DE, Pierson SK, Shilling D, Nemat S, Appiani C, Guilfoyle M, **Tendler C**, van Rhee F, Fajgenbaum DC. Predictors of response to anti-IL6 monoclonal antibody therapy (siltuximab) in idiopathic multicentric Castleman disease: secondary analyses of phase II clinical trial data. *Br J Haematol*. 2019 Jan;184(2):232-241.
24. Greshock J, Lewi M, Hartog B, **Tendler C**. Harnessing Real-World Evidence for the Development of Novel Cancer Therapies. *Trends Cancer*. 2020 Nov; 6(11):907-909.
25. Pierson SK, Shenoy S, Oromendia AB, Gorzewski AM, Langan Pai RA, Nabel CS, Ruth JR, Parente SAT, Arenas DJ, Guilfoyle M, Reddy M, Weinblatt M, Shadick N, Bower M, Pria AD, Masaki Y, Katz L, Mezey J, Beineke P, Lee D, **Tendler C**, Kambayashi T, Fosså A, van Rhee F, Fajgenbaum DC. Discovery and validation of a novel subgroup and therapeutic target in idiopathic multicentric Castleman disease. *Blood Adv*. 2021 Sep 14;5(17):3445-3456.
26. Li BT, Daly B, Gospodarowicz M, Bertagnolli MM, Brawley OW, Chabner BA, Fashoyin-Aje L, de Claro RA, Franklin E, Mills J, Legos J, Kaucic K, Li M, The L, Hou T, Wu T-H, Albrecht B, Shao Y, Finnegan J, Qian J, Shahidi J, Gasal E, **Tendler C**, Kim G, Yan J, Morrow PK, Fuchs CS, Zhang L, LaCaze R, Oelrich S, Murphy MJ, Pazdur R, Rudd K, & Wu Y-L. Reimagining patient-centric cancer clinical trials: a multi-stakeholder international coalition. *Nature Medicine*. 2022 April 28;620–626.
27. Sridhara R, Marchenko O, Jiang Q, Barksdale E, Chen J, Dreyer N, Fashoyin-Aje L, Garrett-Mayer E, Gormley N, Gwise T, Hess L, Mandrekar S, Pignatti F, Rantell K, Raven A, Shen Y-L, Singh H, **Tendler CL**, Theoret M, & Pazdur R. Evaluation of treatment effect in underrepresented population in cancer trials: Discussion with International Regulators. *Statistics in Biopharmaceutical Research*. Published online: 31 Oct 2022; 15(2): 450-456.
28. Fashoyin-Aje LA, **Tendler C**, Lavery B, Ghiorghiu S, Gerald B, Kalidas C, Richie N, Winson K, Warren NJH, Tellman TV, Retzlaff J, Foti M, Pazdur R. Driving Diversity and Inclusion in Cancer Drug Development - Industry and Regulatory Perspectives, Current Practices, Opportunities, and Challenges. *Clin Cancer Res*. 2023 Jun 28:OF1-OF7. doi: 10.1158/1078-0432.CCR-23-1391. Online ahead of print.

29. **Tendler C**, Hong PS, Kane C, Kopaczynski C, Terry W, Emanuel EJ. Academic and Private Partnership to Improve Informed Consent Forms Using a Data Driven Approach. *Am J Bioeth.* 2023 Sep 22:1-3. Online ahead of print.
30. Daly B, Brawley OW, Gospodarowicz MK, Olopade OI, Fashoyin-Aje L, Wolodzko Smart V, Chang IF, **Tendler CL**, Kim G, Fuchs CS, Beg MS, Zhang L, Legos JJ, Duran CO, Kalidas C, Qian J, Finnegan J, Pilarski P, Keane H, Shen J, Silverstein A, Wu Y-L, Pazdur R, Li BT. Remote Monitoring and Data Collection for Decentralized Clinical Trials. *JAMA Netw Open.* 2024;7(4):e246228. doi:10.1001/jamanetworkopen.2024.6228
31. Adewole T, Albrecht B, Beg S, Brawley O,.....**Tendler C**, et al. Advancing Global Health Equity in Oncology Clinical Trial Access. *Cancer Discov.* 2024 Dec 2; 14(12): 2317-2323. doi: 10.1158/2159-8290.CD-24-1288.

ABSTRACTS

1. Tendler CL, Greenberg SJ, Blattner W, Manns A, Waldmann, TA. Variable expression of the HTLV-I regulatory transcript pX in the adult T-cell leukemia (ATL) and the tropical spastic paraparesis (TSP) may reflect different stages of retroviral infection. *Blood*. Abstract 1989;74 (Suppl):764.
2. Greenberg SJ, Tendler CL, Waldmann TA. Transcription of TNF in HTLV-I associated ATL and HAM/TSP: relation to retroviral transactivating gene expression. *J Cell Biochem*. Abstract 1990; (Suppl 14B):47.
3. Tendler CL, Greenberg SJ, Blattner W, Waldmann TA. Immune activation in HTLV-I associated myelopathy is associated with induction of IL-2 and its receptor via the PX transactivator. *Clinical Research*. Abstract 1990;38:460A.
4. Tendler CL, Greenberg S, Burton J, Blattner W, Waldmann TA. Cytokine induction in HTLV-I associated myelopathy/adult T-cell leukemia: alternate molecular mechanisms underlying retroviral pathogenesis. *Blood*. Abstract 1990;76 (Suppl):495.
5. Tendler CL, Milani D, Srivastava D, English M, Licht J, Wilson S. Regulation of the DNA repair enzyme β -polymerase by HIV. *Pediatr Res* 1994;35:171A.
6. Tendler CL, Streeter G, Rios P, Wong O. BCL-2 activation in differentiated neuroblastoma is associated with resistance to chemotherapy- and radiation-induced apoptosis. *J Cell Biochem*. Abstract 1995; (Suppl 19A):86.
7. Pizzolato J, Greenberg D, Streeter G, Manfredi J, Lackner C, Arkin S, Tendler CL. p53 status in AIDS-lymphoma cell lines correlated with sensitivity to chemotherapy and radiation-induced apoptosis. *Blood* 1995;86:739a.
8. Solal-Celigny P, Lepage E, Brousse N, Tertian G, Thyss A, Reman O, Sebban C, Pignon B, Gisselbrecht C, Coiffier B, Cole B, Sugano D, Tendler CL. A doxorubicin containing regimen with or without interferon alpha 2b in advanced follicular lymphomas. Final analysis of survival, toxicity, and quality of life of the GELF 86 trial. *Blood* 1996;88:1800a.
9. Keller AM, Mennel RG, Nabholz J, Georgoulas V, Emanuel D, Tendler CL. Phase III trial of pegylated liposomal doxorubicin (Caelyx/Doxil) for the treatment of patients with advanced breast cancer who have failed a prior taxane-containing chemotherapy regimen. *Proc Am Soc Clin Oncol* 2001;20:30a (abstr. 115).

10. Michallet M, Delain M, Maloisel F, Hellmann A, Rosas A, Silver R, Tendler C. Phase III trial of PEG-Intron vs. Interferon alfa-2b for the initial treatment of chronic myelogenous leukemia (CML). *Blood* 2001; 98:348a (abstr. 1467).
11. Wigler N, Inbar M, O'Brien M, Rosso R, Grischke EM, Santoro A, Alland L, Tendler CL. Reduced cardiac toxicity and comparable efficacy in a phase III trial of pegylated liposomal doxorubicin (Caelyx/Doxil) vs. doxorubicin for first-line treatment of metastatic breast cancer. *Proc Am Soc Oncol* 2002; 21:48a (abstr. 177).
12. Hutson TE, Mekhail T, Messerli E, Molto L, Tannenbaum C, Finke J, Elson P, Dreicer R, Olencki T, Bukowski RM, Tendler CL. Phase I trial of PEG-intron and rIL-2 in patients with metastatic renal cell carcinoma. *Proc Am Soc Oncol* 2002; 21:148b (abstr. 2406).