

- lung cancer: results of a randomized prospective study. *J Thorac Cardiovasc Surg* 106: 703-708, 1993.
- 11) Keller SM, et al: A randomized trial of postoperative adjuvant therapy in patients with completely resected stage II or IIIA non-small-cell lung cancer. Eastern Cooperative Oncology Group. *N Engl J Med* 342: 1217-1222, 2000.
 - 12) Wada H, Hitomi S, Teramatsu T, West Japan Study Group for Lung Cancer Surgery: Adjuvant chemotherapy after complete resection in non-small-cell lung cancer. *J Clin Oncol* 14: 1048-1054, 1996.
 - 13) Wada H, et al: Postoperative adjuvant chemotherapy with PVM (cisplatin+vindesine+mitomycin C) and UFT (uracil+tegafur) in resectable stage I-II NSCLC(non-small cell lung cancer): a randomized clinical trial. West Japan Study Group for lung cancer surgery (WJSG). *Eur J Cardiothorac Surg* 15: 438-443, 1999.
 - 14) Kato H, et al: A randomized phase III study comparing Ubenimex (Bestatin) versus placebo as postoperative adjuvant treatment in patients with stage I squamous cell lung cancer. *Proc Am Soc Clin Oncol* 20: 307 a, 2001.
 - 15) Johnson DH, et al: Thoracic radiotherapy does not prolong survival in patients with locally advanced unresectable non-small cell lung cancer. *Ann Intern Med* 113: 33-38, 1990.
 - 16) Pritchard R, et al: Chemotherapy plus radiotherapy compared with radiotherapy alone in the treatment of locally advanced, unresectable, non-small-cell lung cancer. A meta-analysis. *Ann Intern Med* 125: 723-729, 1996.
 - 17) Marino P, et al: Randomized trials of radiotherapy alone versus combined chemotherapy and radiotherapy in stages IIIa and IIIb non small cell lung cancer. A meta-analysis. *Cancer* 76: 593-601, 1995.
 - 18) Kubota K, et al: Role of radiotherapy in combined modality treatment of locally advanced non-small-cell lung cancer. *J Clin Oncol* 12: 1547-1552, 1994.
 - 19) Sculier JP, et al: A randomized phase III trial comparing consolidation treatment with further chemotherapy to chest irradiation in patients with initially unresectable locoregional non-small-cell lung cancer responding to induction chemotherapy. *Ann Oncol* 10: 295-303, 1999.
 - 20) Furuse K, et al: Phase III study of concurrent versus sequential thoracic radiotherapy in combination with mitomycin, vindesine, and cisplatin in unresectable stage III non-small cell lung cancer. *J Clin Oncol* 17: 2692-2699, 1999.
 - 21) Curran WJ Jr, et al: Phase III comparison of sequential vs concurrent chemoradiation for PTS with unresectable stage III non-small cell lung cancer (NSCLC): initial report of Radiation Therapy Oncology Group (RTOG) 9410. *Proc ASCO* 19: 484 a, 2000.
 - 22) Dillman RO, et al: A randomized trial of induction chemotherapy plus high-dose radiation versus radiation alone in stage III non-small-cell lung cancer. *N Engl J Med* 323: 940-945, 1990.
 - 23) Dillman RO, et al: Improved survival in stage III non-small-cell lung cancer: seven-year follow up of Cancer And Leukemia Group B (CALGB) 8433 trial. *J Natl Cancer Inst* 88: 1210-1215, 1996.
 - 24) Sause WT, et al: Radiation Therapy Oncology Group (RTOG) 88-08 and Eastern Cooperative Oncology Group (ECOG) 4588: preliminary results of a phase III trial in regionally advanced, unresectable non-small-cell lung cancer. *J Natl Cancer Inst* 88: 198-205, 1995.
 - 25) Sause W, et al: Final results of phase III trial in regionally advanced unresectable non-small cell lung cancer: Radiation Therapy Oncology Group, Eastern Cooperative Oncology Group, and Southwest Oncology Group. *Chest* 117: 358-364, 2000.
 - 26) Le Chevalier T, et al: Radiotherapy alone versus combined chemotherapy and radiotherapy in non-resectable non-small cell lung cancer: First analysis of a randomized trial 353 patients. *J Natl Cancer Inst* 83: 417-420, 1991.
 - 27) Arriagada R, et al: Cisplatin-based chemotherapy in patients with locally advanced non-small cell lung cancer: Late analysis of a French randomized trial. *Proc ASCO* 17: 446 a, 1997.
 - 28) Machtay M, et al: Is prolonged survival possible for patients with supraclavicular node metastases in non-small cell lung cancer treated with chemotherapy?: analysis of the Radiation Therapy Oncology Group experience. *Int J Radiat Oncol Biol Phys* 44: 847-853, 1999.
 - 29) Sahake-Koning C, et al: Effects of concomitant cisplatin and radiotherapy on inoperable non-small cell lung cancer. *N Engl J Med*

- 326: 524-530, 1992.
- 30) Jeremic B, et al: Randomized trial of hyperfractionated radiation therapy with or without concurrent chemotherapy for stage III non-small-cell lung cancer. *J Clin Oncol* 13: 452-458, 1995.
- 31) Jeremic B, et al: Hyperfractionated radiation therapy with or without concurrent low-dose daily carboplatin/etoposide for stage III non-small-cell lung cancer: a randomized study. *J Clin Oncol* 14: 1065-1070, 1996.
- 32) Mattson RF, et al: Inoperable non-small cell lung cancer: radiation with or without chemotherapy. *Eur J Cancer Clin Oncol* 24: 477-482, 1988.
- 33) Morton RF, et al: Thoracic radiation therapy alone compared with combined chemoradiotherapy for locally unresectable non-small cell lung cancer. *Ann Intern Med* 115: 737-739, 1991.
- 34) Gregor A, et al: Radical radiotherapy and chemotherapy in inoperable non-small-cell lung cancer: A randomized trial. *J Natl Cancer Inst* 85: 997-999, 1993.
- 35) Trovo MG, et al: Combined radiotherapy and chemotherapy versus radiotherapy alone in locally advanced epidermoid bronchogenic carcinoma: a randomized study. *Cancer* 65: 400-414, 1990.
- 36) Blanke C, et al: Phase III trial of thoracic irradiation with or without cisplatin for locally advanced unresectable non-small-cell lung cancer: A Hooiser Oncology Group Protocol. *J Clin Oncol* 13: 1425-1429, 1995.
- 37) Soresi E, et al: A randomized clinical trial comparing radiation therapy vs radiation therapy plus cis-dichlorodiammine platinum (II) in the treatment of locally advanced non-small cell lung cancer. *Semin Oncol* 15(6 suppl 7): 20-25, 1988.
- 38) Trovo MG, et al: Radiotherapy versus radiotherapy enhance by cisplatin in stage III non-small cell lung cancer. *Int J Radiat Oncol Biol Phys* 24: 11-15, 1992.
- 39) Kubota K, et al: Phase II study of concurrent chemotherapy and radiotherapy for unresectable stage III non-small-cell lung cancer: Long-term follow up results. Japan Clinical Oncology Group Protocol 8902. *Ann Oncol* 11: 445-450, 2000.
- 40) Bunn PA Jr, et al: Chemoradiotherapy with or without granulocyte-macrophage colony-stimulating factor in the treatment of limited-stage small-cell lung cancer: a prospective phase III randomized study of the Southwest Oncology Group. *J Clin Oncol* 13: 1632-1641, 1995.
- 41) The American Society of Clinical Oncology: Update of recommendations for the use of hematopoietic colony-stimulating factor: Evidence-based clinical practice guidelines. *J Clin Oncol* 14: 1957-1960, 1996.
- 42) Clamon G, et al: Radiosensitization with carboplatin for patients with unresectable stage III non-small-cell lung cancer: a phase III trial of the Cancer and Leukemia Group B and the Eastern Cooperative Group. *J Clin Oncol* 17: 4-11, 1999.
- 43) Ball D, et al: A randomized phase III study of accelerated or standard fraction radiotherapy with or without concurrent carboplatin in inoperable non-small cell lung cancer: final report of an Australian multi-centre trial. *Radiother Oncol* 52: 129-136, 1999.
- 44) Goren HJM, et al: Phase III study of continuous carboplatin over 6 weeks with radiation versus radiation alone in stage III non-small cell lung cancer (NSCLC). *Proc ASCO* 18: 466 a, 1999.
- 45) Grilli R, et al: Chemotherapy for advanced non-small cell lung cancer: How much benefit is enough? *J Clin Oncol* 11: 1866-1872, 1993.
- 46) Souquet PJ, et al: Polychemotherapy in advanced non-small cell lung cancer: A meta-analysis. *Lancet* 342: 19-21, 1993.
- 47) Marino P, et al: Chemotherapy vs supportive care in advanced non-small-cell lung cancer: results of a meta-analysis of the literature. *Chest* 106: 861-865, 1994.
- 48) Non-small Cell Lung Cancer Collaborative Group: Chemotherapy for non-small cell lung cancer (Cochrane Review). Cochrane Database Syst Rev: CD 002139, 2002.
- 49) The Elderly Lung Cancer Vinorelbine Italian Study Group: Effects of vinorelbine on quality of life and survival of elderly patients with advanced non-small cell lung cancer. *J Natl Cancer Inst* 91: 66-72, 1999.
- 50) Cullen MH, et al: Mitomycin, ifosfamide, and cisplatin in unresectable non-small-cell lung cancer: Effects on survival and quality of life. *J Clin Oncol* 17: 3188-3194, 1999.
- 51) Thongprasert S, et al: Relationship between quality of life and clinical outcome in advanced non-small cell lung cancer: best supportive care (BSC) versus BSC plus chemotherapy. *Lung Cancer* 24: 17-24, 1999.
- 52) Helsing M, et al: Quality of life and survival in patients with advanced non-small cell lung

- cancer receiving supportive care plus chemotherapy with carboplatin and etoposide or supportive care only. A multicentre randomized phase III trial. Joint Lung Cancer Study Group. *Eur J Cancer* 34: 1036-1044, 1998.
- 52) Crawford J, et al: Randomized trial of vinorelbine compared with fluorouracil plus leucovorin in patients with stage IV non-small-cell lung cancer. *J Clin Oncol* 14: 2774-2784, 1996.
- 53) Anderson H, et al: Gemcitabine plus best supportive care (BSC) vs BSC in inoperable non-small cell lung cancer—a randomized trial with quality of life as the primary outcome. *Br J Cancer* 83(4): 447-453, 2000.
- 54) O'Connell JP, et al: Frequency and prognostic importance of pretreatment clinical characteristics in patients with advanced non-small cell lung cancer treated with combination chemotherapy. *J Clin Oncol* 4: 1604-1614, 1986.
- 55) Albain KS, et al: Survival determinants in extensive-stage non-small cell lung cancer: The Southwest Oncology Group experience. *J Clin Oncol* 9: 1618-1626, 1991.
- 56) Paesmans M, et al: Prognostic factors for survival in advanced non-small cell lung cancer: Univariate and multivariate analysis including recursive partitioning and amalgamation algorithms in 1052 patients. The European Lung Cancer Working Party. *J Clin Oncol* 13: 1221-1230, 1995.
- 57) Johnson DH, et al: E 1594-A randomized phase III trial in metastatic non-small cell lung cancer (NSCLC)—outcome of PS 2 patients (Pts): an Eastern Cooperative Group Trial (ECOG). *Proc ASCO* 18: 461 a, 1999.
- 58) Sweeney CJ, et al: Outcome of patients with a performance status of 2 in Eastern Cooperative Oncology Group study E 1594. A phase III trial in patients with metastatic nonsmall cell lung carcinoma. *Cancer* 92: 2639-2647, 2001.
- 59) Oshita F, et al: Prospective evaluation of the feasibility of cisplatin based chemotherapy for elderly lung cancer patients with normal organ functions. *Jpn J Cancer Res* 86: 118-1202, 1995.
- 60) Langer CJ, et al: Cisplatin-based therapy for elderly patients with advanced non-small-cell lung cancer: Implications of Eastern Cooperative Oncology Group 5592, a randomized trial. *J Natl Cancer Inst* 94: 173-181, 2002.
- 61) Kubota K, et al: Cisplatin-based combination chemotherapy for elderly patients with non-small-cell lung cancer. *Cancer Chemother Pharmacol* 40(6): 469-474, 1997.
- 62) Marino P, et al: Single-agent chemotherapy versus combination chemotherapy in advanced non-small cell lung cancer: a quality and meta-analysis study. *Lung Cancer* 13(1): 1-12, 1995.
- 63) Lilienbaum RC, et al: Single agent versus combination chemotherapy in patients with advanced non-small cell lung carcinoma. A meta-analysis of response, toxicity, and survival. *Cancer* 82: 116-126, 1998.
- 64) Wozniak AJ, et al: Randomized trial comparing cisplatin with cisplatin plus vinorelbine in the treatment of advanced non-small-cell lung cancer: a Southwest Oncology Group study. *J Clin Oncol* 16: 2459-2465, 1998.
- 65) Sandler AB, et al: Phase III trial of gemcitabine plus cisplatin versus cisplatin alone in patients with locally advanced or metastatic non-small-cell lung cancer. *J Clin Oncol* 18: 122-130, 2000.
- 66) Gatzemeier U, et al: Phase III comparative study of high-dose cisplatin versus a combination of paclitaxel and cisplatin in patients with advanced non-small cell lung cancer. *J Clin Oncol* 18(19): 3330-3339, 2000.
- 67) Depierre A, et al: Vinorelbine versus vinorelbine plus cisplatin in advanced non-small cell lung cancer: a randomized trial. *Ann Oncol* 5(1): 37-42, 1994.
- 68) Crino L, et al: A randomized trial of three cisplatin-containing regimens in advanced non-small-cell lung cancer (NSCLC): a study of the Umbrian Lung Cancer Group. *Cancer Chemother Pharmacol* 26: 52-56, 1990.
- 69) Dhingra HM, et al: Randomized trial of three combinations of cisplatin with vindesine and/or VP 16-213 in the treatment of advanced non-small cell lung cancer. *J Clin Oncol* 3: 176-183, 1985.
- 70) Weick JK, et al: A randomized trial of five cisplatin-containing treatments in with metastatic non-small-cell lung cancer: A Southwest Oncology Group Study. *J Clin Oncol* 9: 1157-1162, 1991.
- 71) Shinkai T, et al: A randomized clinical trial of vindesine plus cisplatin versus mitomycin plus vindesine and cisplatin in advanced non-small cell lung cancer. *Eur J Cancer* 27: 571-575, 1991.
- 72) Fukuoka M, et al: A randomized trial in inoperable non-small cell lung cancer: Vindesine and cisplatin versus mitomycin, vindesine and cisplatin versus etoposide and

- cisplatin alternating with vindesine and mitomycin. *J Clin Oncol* 9: 606-613, 1991.
- 73) Sculier J-P, et al: Phase III randomized trial comparing cisplatin and carboplatin with or without ifosfamide in patients with advanced non-small-cell lung cancer. *J Clin Oncol* 16: 1388-1396, 1998.
- 74) Comella P, et al: Randomized trial comparing cisplatin, gemcitabine, and vinorelbine with either cisplatin and gemcitabine or cisplatin and vinorelbine in advanced non-small-cell lung cancer. Interim analysis of a phase III trial of the Southern Italy Cooperative Oncology Group. *J Clin Oncol* 18(7): 1451-1457, 2000.
- 75) Comella P; Southern Italy Cooperative Oncology Group: Phase III trial of cisplatin/gemcitabine with or without vinorelbine or paclitaxel in advanced non-small cell lung cancer. *Semin Oncol* 28(2 Suppl 7): 7-10, 2001.
- 76) Alberola V, et al: Cisplatin/gemcitabine (CG) vs cisplatin/gemcitabine/vinorelbine (CGV) vs sequential doublets of gemcitabine/vinorelbine followed by ifosfamide/vinorelbine (GV/IV) in advanced non-small cell lung cancer (NSCLC): results of a Spanish Lung Cancer Group Phase III Trial (GEPC/98-02). *Proc ASCO* 20: 308 a, 2001.
- 77) Thompson D, et al: Prospective randomized study of four third generation chemotherapy regimens in patients (pts) with advanced non-small cell lung cancer: a Minnie Pearl Cancer Research Network Trial. *Proc ASCO* 20: 314 a, 2001.
- 78) Tan E, et al: Glob 1: Final results of a prospective randomized phase III trial comparing vinorelbine and cisplatin (NP) versus vinorelbine, ifosfamide, and cisplatin (NIP) in metastatic non small cell lung cancer (NSCLC) patients (pts). *Proc ASCO* 20: 326 a, 2001.
- 79) Masuda N, et al: Randomized trial comparing cisplatin (CDDP) and irinotecan (CPT-11) versus CDDP and vindesine (VDS) versus CPT-11 alone in advanced non-small cell lung cancer (NSCLC). *Proc ASCO* 18: 459 a, 1999.
- 80) Niho S, et al: Randomized multicenter phase III trial of irinotecan (CPT-11) and cisplatin (CDDP) versus CDDP and vindesine (VDS) in patient with advanced non-small cell lung cancer. *Proc ASCO* 18: 492 a, 1999.
- 81) Fukuoka M, et al: Impact of irinotecan (CPT-11) and cisplatin (CDDP) on survival in previously untreated metastatic non-small cell lung cancer (NSCLC). *Proc ASCO* 19: 495 a, 2000.
- 82) Bonomi P, et al: Comparison of survival and quality of life in advanced non-small-cell lung cancer patients treated with two dose levels of paclitaxel combined with cisplatin versus etoposide with cisplatin: results of an Eastern Cooperative Oncology Group trial. *J Clin Oncol* 18: 623-631, 2000.
- 83) Giaccone G, et al: Randomized study of paclitaxel-cisplatin versus cisplatin-teniposide in patients with advanced non-small-cell lung cancer. The European Organization for Research and Treatment of Cancer Lung Cancer Cooperative Group. *J Clin Oncol* 16: 2133-2141, 1998.
- 84) Belani CP, et al: Randomized phase III trial comparing cisplatin/etoposide versus carboplatin/paclitaxel in advanced and metastatic non-small cell lung cancer (NSCLC). *Proc ASCO* 17: 455 a, 1998.
- 85) Le Chevalier T, et al: Randomized study of vinorelbine and cisplatin versus vindesine and cisplatin versus vinorelbine alone in advanced non-small-cell lung cancer: results of a European multicenter trial including 612 patients. *J Clin Oncol* 12: 360-367, 1994.
- 86) Le Chevalier T, et al: Long term analysis of survival in the European randomized trial comparing vinorelbine/cisplatin to vindesine/cisplatin and vinorelbine alone in advanced non-small cell lung cancer. *Oncologist* 6(Suppl 1): 8-11, 2001.
- 87) Baldini E, et al: Cisplatin-vindesine-mitomycin (MVP) vs cisplatin-ifosfamide-vinorelbine (PIN) vs carboplatin-vinorelbine (CaN) in patients with advanced non-small-cell lung cancer (NSCLC): a FONICAP randomized phase II study. Italian Lung Cancer Task Force (FONICAP). *Br J Cancer* 77 (12): 2367-2370, 1998.
- 88) Pelot M, et al: Multicenter randomized trial comparing cisplatin-mitomycin-vinorelbine versus cisplatin-mitomycin-vindesine in advanced non-small cell lung cancer. 'Groupe Francais de Pneumo-Cancerologie'. *Lung Cancer* 14: 119-134, 1996.
- 89) Cardenal F, et al: Randomized phase III study of gemcitabine-cisplatin versus etoposide-cisplatin in the treatment of locally advanced or metastatic non-small-cell lung cancer. *J Clin Oncol* 17: 12-18, 1999.
- 90) Crino L, et al: Gemcitabine and cisplatin versus mitomycin, ifosfamide, and cisplatin in advanced non-small-cell lung cancer: a ran-

- domized phase III study of the Italian Lung Cancer project. *J Clin Oncol* 17: 3522-3530, 1999.
- 91) Kunitoh H, et al: Preliminary results of a randomized phase III trial of docetaxel (D) and cisplatin (P) versus vindesine (V) and P in stage IV non small cell lung cancer (NSCLC). *Proc ASCO* 20: 323 a, 2001.
- 92) 梁 尚志: 進行非小細胞肺癌の Cisplatin+旧薬 vs Cisplatin+新薬の meta-analysis. 肺癌 40 (5) 第41回日本肺癌学会総会号: 375, 2000.
- 93) Kelly K, et al: Randomized phase III trial of paclitaxel plus carboplatin versus vinorelbine plus cisplatin in the treatment of patients with advanced non-small cell lung cancer (NSCLC): a Southwest Oncology Group. *J Clin Oncol* 19(13): 3210-3218, 2001.
- 94) Schiller JH, et al: Comparison of four chemotherapy regimens for advanced non-small-cell lung cancer. *N Engl J Med* 346(2): 92-98, 2002.
- 95) Scagliotti GV, et al: Phase III randomized trial comparing three platinum-based doublets in advanced non-small-cell lung cancer. *Proc ASCO* 20: 308 a, 2001.
- 96) Rodriguez J, et al: A multicenter, randomized phase III study of docetaxel+cisplatin (DC) and docetaxel+carboplatin (DCB) vs. vinorelbine+cisplatin (VC) in chemotherapy-naive patients with advanced non-small cell lung cancer. *Proc ASCO* 20: 314 a, 2001.
- 97) Boni C, et al: Bolus versus 5-day continuous infusion of cisplatin with mitomycin and vindesine in the treatment of advanced non-small cell lung cancer (NSCLC): a phase III prospective randomized trial of the Italian Oncology Group for Clinical Research (GIORC). *Eur J Cancer* 34(12): 1974-1976, 1998.
- 98) Goldberg RM, et al: Bolus versus infusion regimens of etoposide and cisplatin in treatment of non-small cell lung cancer: a study of the North Central Cancer Treatment Group. *J Natl Cancer Inst* 82: 1899-1903, 1990.
- 99) Perng RP, et al: Gemcitabine versus the combination of cisplatin and etoposide in patients with inoperable non-small-cell lung cancer in a phase II randomized study. *J Clin Oncol* 15(5): 2097-2102, 1997.
- 100) Vansteenkiste JF, et al: Clinical-benefit response in advanced non-small-cell lung cancer: A multicentre prospective randomized phase III study of single agent gemcitabine versus cisplatin-vindesine. *Ann Oncol* 12(9): 1221-1230, 2001.
- 101) Ranson M, et al: Randomized trial of paclitaxel plus supportive care versus supportive care for patients with advanced non-small-cell lung cancer. *J Natl Cancer Inst* 92(13): 1074-1080, 2000.
- 102) Roszkowski K, et al: A multicenter, randomized, phase III study of docetaxel plus best supportive care in chemotherapy-naive patients with metastatic or non-resectable localized non-small cell lung cancer (NSCLC). *Lung Cancer* 27(3): 145-157, 2000.
- 103) Frasci G, et al: Gemcitabine plus vinorelbine versus vinorelbine alone in elderly patients with advanced non-small-cell lung cancer. *J Clin Oncol* 18(13): 2529-2536, 2000.
- 104) Gridelli C, et al: The MILES (Multicenter Italian Lung Cancer in the Elderly Study) phase 3 trial: gemcitabine+vinorelbine vs vinorelbine and vs gemcitabine in elderly advanced NSCLC patients. *Proc ASCO* 20: 308 a, 2001.
- 105) Georgoulias V, et al: Platinum-based and nonplatinum-based chemotherapy in advanced non-small-cell lung cancer: a randomized multicentre trial. *Lancet* 357(9267): 1478-1484, 2001.
- 106) Satouchi M, et al: Randomized phase II study of docetaxel (DOC) plus cisplatin (CDDP) versus DOC plus irinotecan in advanced non-small cell lung cancer (NSCLC); a West Japan Thoracic Oncology Group (WJTOG) study. *Proc ASCO* 20: 329 a, 2001.
- 107) Kosmidis P: Interim results of a phase III trial. Paclitaxel/carboplatin vs paclitaxel/gemcitabine in advanced non-small-cell lung cancer. *Oncology* 14(suppl 4): 41-48, 2000.
- 108) Van Meerbeeck JP, et al: A EORTC randomized phase III trial of three chemotherapy regimens in advanced non-small cell lung cancer. *Proc ASCO* 20: 308 a, 2001.
- 109) Smith IE, et al: Duration of chemotherapy in advanced non-small-cell lung cancer: a randomized trial of three versus six courses of mitomycin, vinblastine, and cisplatin. *J Clin Oncol* 19(5): 1336-1343, 2001.
- 110) Socinski MA, et al: Phase III trial comparing a defined duration of therapy versus continuous therapy followed by second-line therapy in advanced-stage III B/IV non-small-cell lung cancer. *J Clin Oncol* 20(5): 1335-1343, 2002.
- 111) Buccheri GF, et al: Continuation of chemotherapy versus supportive care alone in patients with inoperable non-small cell lung

- cancer and stable disease after two or three cycles of MACC. Results of a randomized prospective study. *Cancer* 63(3): 428-432, 1989.
- 112) Inoperable non-small-cell lung cancer (NSCLC): a Medical Research Council randomized trial of palliative radiotherapy with two fractions or ten fractions. Report to the Medical Research Council by its Lung Cancer Working Party. *Br J Cancer* 63: 265-270, 1991.
- 113) Fossella, FV, et al: Randomized phase III trial of docetaxel versus vinorelbine or ifosfamide in patients with advanced non-small-cell lung cancer previously treated with platinum-containing chemotherapy regimens. *J Clin Oncol* 18(12): 2354-2362, 2000.
- 114) Shepherd FA, et al: Prospective randomized trial of docetaxel versus best supportive care in patients with non-small-cell lung cancer previously treated with platinum-based chemotherapy. *J Clin Oncol* 18: 2095-2103, 2000.
- 115) Mukohara T, et al: Japanese experience with second-line chemotherapy with low-dose (60 mg/m²) docetaxel in patients with advanced non-small-cell lung cancer. *Cancer Chemother Pharmacol* 48(5): 356-360, 2001.
- 116) Crino L, et al: Gemcitabine as second-line treatment for advanced non-small-cell lung cancer. A phase II trial. *J Clin Oncol* 17(7): 2181-2185, 1999.
- 117) Rossi A, et al: Activity of gemcitabine (GEM) in cisplatin pretreated patients with advanced non-small cell lung cancer (NSCLC): a phase 2 trial. *Proc ASCO* 18: 484a, 1999.
- 118) Baas P, et al: Second line gemcitabine (G) therapy in non-small cell lung cancer (NSCLC) stage IIIb and IV. *Proc ASCO* 18: 495 a, 1999.
- 119) Reddy GR, et al: Gemcitabine (GEM) in platinum (PLAT) treated non-small cell lung cancer(NSCLC). *Proc ASCO* 18: 521 a, 1999.
- 120) Fox W, et al: Medical Research Council comparative trial of surgery and radiotherapy for primary treatment of small-celled or oat-celled carcinoma of bronchus. *Lancet* 2: 63-65, 1973.
- 121) Green RA, et al: Alkylating agents in bronchogenic carcinoma. *Am J Med* 46: 516-525, 1969.
- 122) Bergsagel DE, et al: Lung cancer: clinical trial of radiotherapy alone vs radiotherapy plus cyclophosphamide. *Cancer* 30: 621, 1972.
- 123) Medical Research Council Lung Cancer Working Party. Radiotherapy alone or with chemotherapy in the treatment of small-cell carcinoma of the lung. *Br J Cancer* 40: 1-10, 1979.
- 124) Petrovich Z, et al: Clinical research on the treatment of locally advanced lung cancer: final report of VALG protocol 13 limited. *Cancer* 42: 1129-1134, 1978.
- 125) Pignon J-P, et al: A meta-analysis of thoracic radiotherapy for small-cell lung cancer. *N Engl J Med* 327: 1618-1624, 1992.
- 126) Warde P, et al: Does thoracic irradiation improve survival and local control in limited-stage small-cell carcinoma of the lung? A meta-analysis. *J Clin Oncol* 10: 890-895, 1992.
- 127) Tsukada H, et al: Japan Clinical Oncology Lung Cancer Study Group. Concurrent vs sequential radiotherapy for small cell lung cancer. *Semin Oncol* 28(2 suppl 4): 23-26, 2001.
- 128) Gregor A, et al: Randomized trial of alternating versus sequential radiotherapy/chemotherapy in limited-disease patients with small-cell lung cancer: a European Organization for Research and Treatment of Cancer Lung Cancer Cooperative Group Study. *J Clin Oncol* 15(8): 2840-2849, 1997.
- 129) Lebeau B, et al: A randomized clinical trial comparing concurrent and alternating thoracic irradiation for patients with limited small cell lung carcinoma. "Petites Cellules" Group. *Cancer* 86(8): 1480-1487, 1999.
- 130) Murray N, et al: Importance of timing for thoracic irradiation in the combined modality treatment of limited-disease small-cell lung cancer. The National Cancer Institute of Canada Clinical Trials Group. *J Clin Oncol* 11(2): 336-344, 1993.
- 131) Jeremic B, et al: Initial versus delayed accelerated hyperfractionated radiation therapy and concurrent chemotherapy in limited small-cell lung cancer: a randomized study. *J Clin Oncol* 15(3): 893-900, 1997.
- 132) Perry MC, et al: Chemotherapy with or without radiation therapy in limited small-cell carcinoma of the lung. *N Engl J Med* 316(15): 912-918, 1987.
- 133) Perry MC, et al: Thoracic radiation therapy added to chemotherapy for small-cell lung cancer: an update of Cancer and Leukemia Group B Study 8083. *J Clin Oncol* 16(7): 2466-2467, 1998.
- 134) Work E, et al: Randomized study of initial

- versus late chest irradiation combined with chemotherapy in limited-stage small-cell lung cancer. Aarhus Lung Cancer Group. *J Clin Oncol* 15(9): 3030-3037, 1997.
- 135) Skatlos DV, et al: Randomized comparison of early versus late hyperfractionated thoracic irradiation concurrently with chemotherapy in limited disease small-cell lung cancer: a randomized phase II study of the Hellenic Cooperative Oncology Group (HeCOG). *Ann Oncol* 12(9): 1231-1238, 2001.
- 136) Turrisi AT, et al: Twice-daily compared with once-daily thoracic radiotherapy in limited small-cell lung cancer treated concurrently with cisplatin and etoposide. *N Engl J Med* 340: 265-271, 1999.
- 137) Suzuki K, et al: Phase II trial of postoperative adjuvant cisplatin/etoposide (PE) in patients with completely resected stage I-III A small cell lung cancer (SCLC): the Japan Clinical Oncology Lung Cancer Study Group Trial (JCOG 9101). *Proc ASCO* 19: 492a, 2000.
- 138) Spiegelman D, et al: Prognostic factors in small-cell carcinoma of the lung: an analysis of 1, 521 patients. *J Clin Oncol* 7(3): 344-354, 1989.
- 139) Albain KS, et al: Determinations of improved outcome in small-cell lung cancer: an analysis of the 2, 580-patient Southwest Oncology Group data base. *J Clin Oncol* 8(9): 1563-1574, 1990.
- 140) Kawahara M, et al: Prognostic factors and prognostic staging system for small cell lung cancer. *Jpn J Clin Oncol* 27(3): 158-165, 1997.
- 141) Sauragi T, et al: Retrospective analysis of the treatment of patients with small cell lung cancer showing poor performance status. *Jpn J Clin Oncol* 26(3): 128-133, 1996.
- 142) Souhami RL, et al: Five-day oral etoposide treatment for advanced small-cell lung cancer: Randomized comparison with intravenous chemotherapy. *J Natl Cancer Inst* 89(8): 577-580, 1997.
- 143) Girling DJ: Comparison of oral etoposide and standard intravenous multidrug chemotherapy for small-cell lung cancer: a stopped multicentre randomized trial. Medical Research Council Lung Cancer Working Party. *Lancet* 348(9027): 563-566, 1996.
- 144) Zelen M: Keynote address on biostatistics and data retrieval. *Cancer Chemother Rep* 34(2): 31-42, 1973.
- 145) Siu LL, et al: Influence of age on the treatment of limited-stage small-cell lung cancer. *J Clin Oncol* 14: 821-828, 1996.
- 146) Okamoto H, et al: Phase II study of area under the plasma-concentration-versus-time curve-based carboplatin plus standard-dose intravenous etoposide in elderly patients with small-cell lung cancer. *J Clin Oncol* 17: 3540-3545, 1999.
- 147) Yuen AR, et al: Similar outcome of elderly patients in intergroup trial 0096: cisplatin, etoposide, and thoracic radiotherapy administered once or twice daily in limited stage small cell lung cancer. *Cancer* 89(9): 1953-1960, 2000.
- 148) Bonner JA, et al: Phase III comparison of twice-daily split-course irradiation versus once-daily irradiation for patients with limited stage small-cell lung carcinoma. *J Clin Oncol* 17(9): 2681-2691, 1999.
- 149) Yokayama A, et al: Dose-finding study of irinotecan and cisplatin plus concurrent radiotherapy for unresectable stage III non-small cell lung cancer. *Br J Cancer* 78(2): 257-262, 1998.
- 150) Oka M, et al: Phase I study of irinotecan and cisplatin with concurrent split-course radiotherapy in unresectable and locally advanced non-small cell lung cancer. *Eur J Cancer* 37(11): 1359-1365, 2001.
- 151) Kudoh S, et al: Phase II study of irinotecan combined with cisplatin in patients with previously untreated small-cell lung cancer. *J Clin Oncol* 16: 1068-1074, 1998.
- 152) Arriagada R, et al: Initial chemotherapeutic doses and survival in patients with limited small-cell lung cancer. *N Engl J Med* 329: 1848-1852, 1993.
- 153) Elias AD, et al: Intrusive combined modality therapy for limited-stage small-cell lung cancer. *J Natl Cancer Inst* 85: 559-566, 1993.
- 154) Beith JM, et al: Long-term follow-up of a randomized trial of combined chemotherapy induction treatment, with and without maintenance chemotherapy in patients with small cell carcinoma of the lung. *Eur J Cancer* 32A(3): 438-443, 1996.
- 155) Edmonson JH, et al: Cyclophosphamide and CCNU in the treatment of inoperable small cell carcinoma and adenocarcinoma for the lung. *Cancer Treat Rep* 60: 925-932, 1976.
- 156) Alberto P, et al: Treatment of bronchogenic carcinoma with simultaneous or sequential combination chemotherapy, including methotrexate, cyclophosphamide, procarbazine and vincristine. *Cancer* 38: 2208-2216, 1976.
- 157) Lowenbraun S, et al: The superiority of com-

- bination chemotherapy over single agent chemotherapy in small cell lung carcinoma. *Cancer* 44: 406-413, 1979.
- 158) Hong WK, et al: Etoposide combined with cyclophosphamide plus vincristine compared with doxorubicin plus cyclophosphamide plus vincristine and with high-dose cyclophosphamide plus vincristine in the treatment of small cell carcinoma of the lung: a randomized trial of the Bristol Lung Cancer Study Group. *J Clin Oncol* 7: 450, 1989.
- 159) Jackson DV, et al: Improvement of long-term survival in extensive small cell lung cancer. *J Clin Oncol* 6: 1161-1169, 1988.
- 160) Messeih AA, et al: Addition of etoposide to cyclophosphamide, doxorubicin, and vincristine for remission induction and survival in patients with small cell lung cancer. *Cancer Treat Rep* 71: 61-66, 1987.
- 161) Lowenbraun S, et al: Combination chemotherapy in small cell lung carcinoma: a randomized study of two intensive regimens. *Cancer* 54: 2344-2350, 1984.
- 162) Fukuoka M, et al: Randomized trial of cyclophosphamide, doxorubicin, and vincristine versus cisplatin and etoposide versus alternation of these regimens in small-cell lung cancer. *J Natl Cancer Inst* 83: 855-861, 1991.
- 163) Roth BJ, et al: Randomized study of cyclophosphamide, doxorubicin, and vincristine versus etoposide and cisplatin versus alternation of these two regimens in extensive small-cell lung cancer: a phase III trial of the southeastern cancer study group. *J Clin Oncol* 10: 282-291, 1992.
- 164) Evans WK, et al: Superiority of alternating non-cross-resistant chemotherapy in extensive small cell lung cancer. A multicentre, randomized trial by the National Cancer Institute of Canada. *Ann Intern Med* 107: 451-458, 1987.
- 165) Evans WK, et al: Etoposide (VP-16) and cisplatin: an effective treatment for relapse of small-cell lung cancer. *J Clin Oncol* 3: 65-71, 1985.
- 166) Porter LL 3 rd, et al: Cisplatin and etoposide combination chemotherapy for refractory small cell carcinoma of the lung. *Cancer Treat Rep* 69: 479-481, 1985.
- 167) Pujol J-L, et al: Is there a case for cisplatin in the treatment of small-cell lung cancer? A meta-analysis of randomized trials of a cisplatin-containing regimen versus a regimen without this alkylating agent. *Br J Cancer* 83(1): 8-15, 2000.
- 168) Ihde DC, et al: Prospective randomized comparison of high-dose and standard-dose etoposide and cisplatin chemotherapy in patients with extensive-stage small-cell lung cancer. *J Clin Oncol* 12(10): 2022-2034, 1994.
- 169) Miller AA, et al: Schedule dependency of 21-day oral versus 3-day intravenous etoposide in combination with intravenous cisplatin in extensive-stage small-cell lung cancer: a randomized phase III study of the Cancer and Leukemia Group B. *J Clin Oncol* 13(8): 1871-1879, 1995.
- 170) Loehrer PJ Sr, et al: Cisplatin plus etoposide with and without ifosfamide in extensive small-cell lung cancer: a Hoosier Oncology Group study. *J Clin Oncol* 13(10): 2594-2599, 1995.
- 171) Miyamoto H, et al: A phase III comparison of etoposide/cisplatin with or without added ifosfamide in small-cell lung cancer. *Oncology* 49(6): 431-435, 1992.
- 172) Mavroudis D, et al: A multicentre randomized clinical trial comparing paclitaxel-cisplatin-etoposide versus cisplatin-etoposide as first-line treatment in patients with small-cell lung cancer. *Ann Oncol* 12(4): 463-470, 2001.
- 173) Pujol JL, et al: Etoposide plus cisplatin with or without the combination of 4'-epidoxorubicin plus cyclophosphamide in treatment of extensive small-cell lung cancer: a French Federation of Cancer Institutes multicentre phase III randomized study. *J Natl Cancer Inst* 93(4): 300-308, 2001.
- 174) Urban T, et al: The addition of cisplatin to cyclophosphamide-doxorubicin-etoposide combination chemotherapy in the treatment of patients with small cell lung carcinoma: a randomized study of 457 patients. "Petites Cellules" Group. *Cancer* 86(11): 2238-2245, 1999.
- 175) Noda K, et al: Irinotecan plus cisplatin compared with etoposide plus cisplatin for extensive small-cell lung cancer. *N Engl J Med* 346: 85-91, 2002.
- 176) Sculier JP, et al: Multiple drug weekly chemotherapy versus combination regimen in small cell lung cancer: a phase III randomized study conducted by the European Lung Cancer Working Party. *J Clin Oncol* 11(10): 1858-1865, 1993.
- 177) Souhami RL, et al: Randomized trial comparing weekly versus 3-week chemotherapy in small cell lung cancer: a Cancer Research Campaign trial. *J Clin Oncol* 12(9): 1806-

- 1813, 1994.
- 178) Furuse K, et al: Phase III study of intensive weekly chemotherapy with recombinant human granulocyte colony-stimulating factor versus standard chemotherapy in extensive-disease small-cell lung cancer. *J Clin Oncol* 16: 2126-2132, 1998.
- 179) Murray N, et al: A randomized study of CODE versus alternating CAV/EP for extensive stage small cell lung cancer: an intergroup study of the National Cancer Institute of Canada Clinical Trials Group and Southwest Oncology Group. *J Clin Oncol* 17(8): 2300-2308, 1999.
- 180) Sculier JP, et al: A three-arm phase III randomized trial assessing, in patients with extensive-disease small-cell lung cancer, accelerated chemotherapy with support of haematological growth factor or oral antibiotics. *Br J Cancer* 85(10): 1444-1451, 2001.
- 181) Johnson DH, et al: A randomized comparison of high-dose versus conventional-dose cyclophosphamide, doxorubicin, and vincristine for extensive-stage small-cell lung cancer: a phase III trial of the Southeastern Cancer Study Group. *J Clin Oncol* 5: 1731-1738, 1987.
- 182) Armitage JO: Bone marrow transplantation. *N Engl J Med* 330: 827-838, 1994.
- 183) Skarlos DV, et al: Randomized comparison of etoposide-cisplatin vs. etoposide-carboplatin and irradiation in small-cell lung cancer. *Ann Oncol* 5: 601-607, 1994.
- 184) Matsui K, et al: Phase II trial of carboplatin plus oral etoposide for elderly patients with small-cell lung cancer. *Br J Cancer* 77(11): 1961-1965, 1998.
- 185) Quoix E, et al: Etoposide phosphate with carboplatin in the treatment of elderly patients with small-cell lung cancer: a phase II study. *Ann Oncol* 12(7): 957-962, 2001.
- 186) Giaccone G, et al: Maintenance chemotherapy in small-cell lung cancer: long-term results of a randomized trial. *J Clin Oncol* 11: 1230-1240, 1993.
- 187) The Medical Research Council by its Lung Cancer Working Party: Controlled trial of twelve versus six courses of chemotherapy in the treatment of small-cell lung cancer. *Br J Cancer* 59: 584-590, 1989.
- 188) Bleehen NM, et al: A randomized trial of three or six courses of etoposide cyclophosphamide methotrexate and vincristine or six courses of etoposide and ifosfamide in small cell lung cancer (SCLC). I: survival and prognostic factors. Medical Research Council Lung Cancer Working Party. *Br J Cancer* 68(6): 1150-1156, 1993.
- 189) Spiro SG, et al: Duration of chemotherapy in small cell lung cancer: a Cancer Research Campaign trial. *Br J Cancer* 59: 578-583, 1989.
- 190) Veslemes M, et al: Optimal duration of chemotherapy in small cell lung cancer: a randomized study of 4 versus 6 cycles of cisplatin-etoposide. *J Chemother* 10(2): 136-140, 1998.
- 191) Schiller JH, et al: Topotecan versus observation after cisplatin plus etoposide in extensive-stage small-cell lung cancer: E 7593-a phase III trial of the Eastern Cooperative Oncology Group. *J Clin Oncol* 19(8): 2114-2122, 2001.
- 192) Ettinger DS, et al: A randomized comparison of standard chemotherapy versus alternating chemotherapy and maintenance versus no maintenance therapy for extensive-stage small-cell lung cancer: a phase III study of the Eastern Cooperative Oncology Group. *J Clin Oncol* 8(2): 230-240, 1990.
- 193) Sculier JP, et al: Randomized trial comparing induction chemotherapy versus induction chemotherapy followed by maintenance chemotherapy in small-cell lung cancer. European Lung Cancer Working Party. *J Clin Oncol* 14(8): 2337-2344, 1996.
- 194) Hanna NH, et al: Maintenance daily oral etoposide versus no further therapy following induction chemotherapy with etoposide plus ifosfamide plus cisplatin in extensive small-cell lung cancer: a Hoosier Oncology Group randomized study. *Ann Oncol* 13: 95-102, 2002.
- 195) Ebi N, et al: Second-line chemotherapy for relapsed small cell lung cancer. *Jpn J Clin Oncol* 27(3): 166-169, 1997.
- 196) Johnson DH, et al: Prolonged administration of oral etoposide in patients with relapsed or refractory small cell lung cancer: a phase II trial. *J Clin Oncol* 8(10): 1613-1617, 1990.
- 197) von Pawel J, et al: Topotecan versus cyclophosphamide, doxorubicin, and vincristine for the treatment of recurrent small-cell lung cancer. *J Clin Oncol* 17(2): 658-667, 1999.
- 198) Groen HJ, et al: Paclitaxel and carboplatin in the treatment of small-cell lung cancer patients resistant to cyclophosphamide, doxorubicin, and etoposide: a non-cross-resistant schedule. *J Clin Oncol* 17: 927-932, 1999.
- 199) Masuda N, et al: Combination of irinotecan

and etoposide for treatment of refractory or
relapsed small-cell lung cancer. *J Clin Oncol*

16: 3329-3334, 1998.
