



*This list of clinical research protocols relating to head and neck cancers is compiled for your convenience.*

*For more information on these protocols, please call PDQ, a service of the National Cancer Institute, at 1-800-4-CANCER. The PDQ Web site is accessible at [http://www.cancer.gov/clinical\\_trials](http://www.cancer.gov/clinical_trials).*

*A searchable Web site developed by the National Library of Medicine is also available at <http://clinicaltrials.gov>.*

## SELECTED CLINICAL RESEARCH PROTOCOLS FOR HEAD AND NECK CANCER

### Diagnosis

**E-4393** Molecular Analysis of Surgical Margins and Regional Lymph Nodes in Patients With Squamous Cell Carcinoma of the Head and Neck

Chairperson: Wayne M. Koch. Telephone: 410-955-4906. Lead organization: Eastern Cooperative Oncology Group. Age range: 18 and over.

### Support

**NCI-V93-0288, SCCC-92110**

Phase II/III Randomized Pilot Study of Fluconazole as Prophylaxis for Mucositis/Thrush in Patients With Head and Neck Cancer Undergoing Radiotherapy

Chairperson: Arnold Markoe. Telephone: 305-243-4319. Lead organization: Sylvester Cancer Center, University of Miami. Age range: over 21.

**DAIICHI-2011A-PRT003/004, UCLA-0104045** Phase III Randomized Study of Cevimeline in Patients With Xerostomia Secondary to Radiotherapy for Cancer in the Head and Neck Region

Chairperson: Milayna Subar. Telephone: 201-573-7104. Lead organization: Daiichi Pharmaceutical Corp. Age range: 18 and over.

**NCI-P00-0177, RTOG-9901** Phase III Randomized Study of Sargramostim (GM-CSF) for Reduction of Radiotherapy-Induced Oral Mucositis in Patients With Head and Neck Cancer Receiving Radiotherapy

Chairperson: Francis G. Le-

Veque. Telephone: 313-745-9300. Lead organization: Radiation Therapy Oncology Group. Age range: not specified.

**CCCWFU-0009, CCCWFU-97300, CCCWFU-BG00-228, NCI-P00-0174** Phase III Randomized Study of the Effect of Megestrol on Weight and Quality of Life in Patients With Head and Neck Cancer

Chairperson: Kathryn McConnell Greven. Telephone: 336-716-4981. Lead organization: Comprehensive Cancer Center at Wake Forest University. Age range: over 18.

**CAN-NCIC-HN3** Phase III Study Comparing the Incidence of Acute Oral Mucositis in Patients With Squamous Cell Carcinoma of the Oral Cavity, Pharynx, or Larynx Receiving Radiotherapy in the Morning or in the Afternoon

Chairperson: Georg Bjarnason. Telephone: 416-480-4928. Lead organization: NCIC-Clinical Trials Group. Age range: 16 and over.

### Phase I

**NCI-01-DC-0006, NCI-3210** Phase I Pilot Study of Recombinant Fowlpox-TRICOM Vaccine in Patients With Advanced Squamous Cell Carcinoma of the Head and Neck

Chairperson: Erik Kass. Telephone: 301-402-0409. Lead organization: National Institute on Deafness and Other Communication Disorders. Age range: 18 and over.

**NCI-2630, UCCRC-11033** Phase I Study of Bevacizumab,

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Fluorouracil, and Hydroxyurea With Concurrent Radiotherapy in Patients With Advanced Head and Neck Cancer

Chairperson: Everett E. Vokes. Telephone: 773-834-0783. Lead organization: University of Chicago Cancer Research Center. Age range: 18 and over.

**NCI-G00-1908, NYU-9955, ROCHE-NYU-9955** Phase I Study of Capecitabine and Cisplatin in Patients With Locally Advanced or Metastatic Cancer of the Upper Gastrointestinal Tract, Head and Neck, Lung, Breast, or Carcinoma of Unknown Primary

Chairperson: Franco M. Muggia. Telephone: 212-263-6485. Lead organization: NYU School of Medicine's Kaplan Comprehensive Cancer Center. Age range: 18 and over.

**DFCI-99274, NCI-G00-1833** Phase I Study of Docetaxel With Concurrent Boost Radiotherapy in Patients With Advanced Squamous Cell Carcinoma of the Head and Neck Previously Treated With Induction Chemotherapy

Chairperson: Roy B. Tishler. Telephone: 617-667-2345. Lead organization: Dana-Farber Cancer Institute. Age range: 18 and over.

**NCI-01-C-0104, NCI-751** Phase I Study of PS-341 and Radiotherapy in Patients With Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck

Chairperson: Carter Van Waes. Telephone: 301-402-4216. Lead organization: National Institute on Deafness and Other Communication Disorders. Age range: over 18.

**CWRU-1399, NCI-T99-0084** Phase I Study of SU5416 and Paclitaxel in Patients With Recurrent, Locally Advanced or Metastatic Cancer of the Head and Neck

Chairperson: Scot C. Remick. Telephone: 216-844-5412. Lead organization: Ireland Cancer Center. Age range: 18 and over.

**NCI-4551, UCHSC-01460** Phase I Study of ZD 1839 and Radiotherapy With or Without Cisplatin in Patients With Locally Advanced Squamous Cell Carcinoma of the Head and Neck

Chairperson: David Raben. Telephone: 720-848-0100. Lead organization: University of Colorado Cancer Center. Age range: 18 and over.

**NCI-5380, PMH-PHL-002** Phase I/II Study of Erlotinib and Cisplatin in Patients With Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck

Chairperson: Lillian Siu. Telephone: 416-946-2911. Lead organization: Princess Margaret Hospital. Age range: 18 and over.

**UAB-F970430006, NCI-G99-1656, UAB-RAD-9601** Phase I/II Study of High Dose Postoperative Reirradiation in Patients With Recurrent or Second Primary Carcinoma of the Head and Neck

Chairperson: Sharon A. Spencer. Telephone: 205-934-2760. Lead organization: University of Alabama at Birmingham Comprehensive Cancer Center. Age range: 18 and over.

**ALZA-97-024-ii, MGH-M7-20, NCI-V98-1384** Phase I/II Study of

Paclitaxel, Amifostine, and Accelerated Hyperfractionated Radiotherapy in Patients With Stage III or IV Head and Neck Cancer

Chairperson: Philip Crawford Amrein. Telephone: 617-726-8748. Lead organization: Massachusetts General Hospital Cancer Center. Age range: 18 and over.

## Phase II

**E-E2301** Phase II Randomized Study of BMS-247550 in Patients With Metastatic or Recurrent Squamous Cell Carcinoma of the Head and Neck

Chairperson: Robert L. Comis. Telephone: 215-789-3609. Lead organization: Eastern Cooperative Oncology Group. Age range: 18 and over.

**RTOG-H-0024** Phase II Study of Adjuvant Paclitaxel Followed By Radiotherapy With Concurrent Paclitaxel and Cisplatin in Patients With Resected High-Risk Stage III or IV Squamous Cell Carcinoma of the Head and Neck

Chairperson: Randal S. Weber. Telephone: 215-662-4665. Lead organization: Radiation Therapy Oncology Group. Age range: 21 and over.

**ONYX-015-003** Phase II Study of Cisplatin, Fluorouracil, and Intratumoral ONYX-015 in Patients With Squamous Cell Carcinoma of the Head and Neck Refractory to Cisplatin and Fluorouracil

Chairperson: Sherry Toney. Telephone: 510-262-8773. Lead organization: ONYX Pharmaceuticals. Age range: 18 and over.

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**MDA-ID-99334, NCI-610** Phase II Study of Fenretinide in Patients With Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck

Chairperson: Fadlo Khuri. Telephone: 713-792-6363. Lead organization: University of Texas - MD Anderson Cancer Center. Age range: 18 and over.

**MB-401, NCI-00-C-0128, NCI-T99-0066** Phase II Study of Flavopiridol in Patients With Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck

Chairperson: Edward Sausville. Telephone: 301-496-4345. Lead organization: Center for Cancer Research. Age range: 18 and over.

**NCI-G97-1159, NU-V96N1, UCCRC-8176** Phase II Study of Hyperfractionated FHX Chemoradiotherapy (Hyper-FHX) With Concomitant Fluorouracil and Hydroxyurea for Intermediate Stage Carcinoma of the Head and Neck

Chairperson: Everett E. Vokes. Telephone: 773-834-0783. Lead organization: University of Chicago Cancer Research Center. Age range: not specified.

**NCI-G99-1587, NU-C98N1, UCCRC-9502** Phase II Study of Induction Chemotherapy With Carboplatin and Paclitaxel Followed by Concurrent Fluorouracil, Hydroxyurea, Paclitaxel, and Hyperfractionated Radiotherapy in Patients With Previously Untreated Advanced Oral, Pharyngeal, or Laryngeal Cancer

Chairperson: Athanassios Argiris. Telephone: 312-695-4441. Lead organization: Robert H. Lurie

Comprehensive Cancer Center, Northwestern University. Age range: 15-80

**E-E3301** Phase II Study of Irinotecan and Docetaxel in Patients With Metastatic or Locally Recurrent Head and Neck Cancer

Chairperson: Robert L. Comis. Telephone: 215-789-3609. Lead organization: Eastern Cooperative Oncology Group. Age range: 18 and over.

**BANYU-RC749J205-01, PRA-RC749J205-01, PRA-WIRB-20001963** Phase II Study of J-107088 in Patients With Advanced Squamous Cell Carcinoma of the Head and Neck

Chairperson: Sherry McGuire. Telephone: 732-578-5523. Lead organization: Pharmaceutical Research Associates Inc. Age range: 18 and over.

**RTOG-9911, RTOG-DEV-1050** Phase II Study of Paclitaxel, Cisplatin, and Filgrastim (G-CSF) Combined With Radiotherapy in Patients With Previously Irradiated Locally Recurrent Squamous Cell Cancer of the Head and Neck

Chairperson: Corey Jay Langer. Telephone: 215-728-2416. Lead organization: Radiation Therapy Oncology Group. Age range: 18 and over.

**SWOG-S0007** Phase II Study of Paclitaxel, Cisplatin, and Fluorouracil in Patients With Metastatic or Recurrent Squamous Cell Carcinoma of the Head and Neck

Chairperson: Maha Hadi A. Husain. Telephone: 313-745-8296. Lead organization: Southwest

Oncology Group. Age range: 18 and over.

**MSKCC-00049, NCI-79** Phase II Study of SU5416 in Patients With Advanced or Recurrent Squamous Cell Carcinoma of the Head and Neck

Chairperson: David G. Pfister. Telephone: 646-422-4461. Lead organization: Memorial Sloan-Kettering Cancer Center. Age range: 18 and over.

**NCI-97-C-0141A, NCI-T96-0078** Phase II Study of Vaccine Therapy With Tumor-Specific Mutated Ras Peptides in Combination With Interleukin-2 and/or Sargramostim (GM-CSF) in Adults With Metastatic Solid Tumors

Chairperson: Samir N. Khleif. Telephone: 301-435-5392. Lead organization: Center for Cancer Research. Age range: 18 and over.

**NCI-1701, UUMC-8429-01** Phase II Study of ZD 1839 in Patients With Recurrent and/or Metastatic Squamous Cell Cancer of the Head and Neck

Chairperson: Richard H. Wheeler. Telephone: 801-585-0601. Lead organization: Huntsman Cancer Institute. Age range: 18 and over.

### Phase III

**INTROGEN-T301** Phase III Randomized Study of Ad5CMV-p53 Gene Therapy (INGN 201) Versus Methotrexate in Patients With Refractory Squamous Cell Carcinoma of the Head and Neck (T301)

Chairperson: Sonya Fisher. Telephone: 713-610-4011. Lead

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organization: Introgen Therapeutics, Inc. Age range: 18 and over.

**EU-20121, ISRCTN-62576956, MRC-CH03** Phase III Randomized Study of Adjuvant Continuous Hyperfractionated Accelerated Radiotherapy Versus Conventional Radiotherapy in Patients With Head and Neck Cancer

Chairperson: M. I. Saunders. Telephone: 0923-844533 (Northwood, England). Lead organization: Medical Research Council Clinical Trials Unit. Age range: not specified.

**INTROGEN-T302** Phase III Randomized Study of Cisplatin and Fluorouracil With or Without Ad5CMV-p53 Gene Therapy (INGN 201) in Patients With Recurrent Squamous Cell Carcinoma of the Head and Neck (T302)

Chairperson: Sonya Fisher. Telephone: 713-610-4011. Lead organization: Introgen Therapeutics, Inc. Age range: 18 and over.

**DFCI-99052, NCI-G99-1630, RP-56976-V-324** Phase III Randomized Study of Neoadjuvant Cisplatin and Fluorouracil With or Without Docetaxel Followed by Chemoradiotherapy in Patients With Locally Advanced Squamous Cell Carcinoma of the Head and Neck

Chairperson: Marshall R. Posner. Telephone: 617-632-3090. Lead organization: Dana-Farber Cancer Institute. Age range: 18 and over.

**RTOG-9903, RTOG-DEV-1008** Phase III Randomized Study of Radiotherapy With or Without Epoetin Alfa in Anemic Patients

With Squamous Cell Carcinoma of the Head and Neck

Chairperson: Mitchell Machtay. Telephone: 215-662-2428. Lead organization: Radiation Therapy Oncology Group. Age range: 18 and over.