

New Drugs Offer Options to Colorectal Cancer Patients

Research Results

Recently, the Food and Drug Administration (FDA) approved two new monoclonal antibodies Erbitux (cetuximab) and Avastin (bevacizumab) were approved by the FDA for use in the treatment of metastatic colon cancer. Antibodies are specialized proteins that your body produces in response to specific antigens. The two are attracted to each other so that the antibody can destroy the antigen. Monoclonal antibodies are produced in the laboratory and are used as targeted treatments in cancer.

Erbitux was approved for treatment in patients with metastatic colon cancer who are no longer responding to Camptosar (irinotecan). Erbitux can be used with Camptosar or alone if the patient cannot tolerate Camptosar. Patients may be responding to Camptosar but able to tolerating the treatment. Erbitux targets a protein called epidermal growth factor receptor (EGFR), which plays a role in regulating cell growth. While this combination (Erbitux and Camptosar) has not improved overall survival, it has shrunk tumors in 22.9% of patients who were no longer responding to Camptosar. When given alone, Erbitux shrank tumors in 10.8% of patients.

Avastin was approved for first-line treatment of patients with metastatic colon cancer. It is approved for use with the chemotherapy regimen IFL or "Saltz regimen" (irinotecan, 5-fluorouracil (5FU) and leucovorin). Avastin targets a protein called vascular endothelial growth factor (VEGF), which stimulates new blood vessel formation. Patients receiving Avastin plus IFL had a 5-month increase in median survival compared to patients receiving IFL alone (20.3 months versus 15.6 months). Progression-free survival was also increased by more than four months for patients receiving Avastin plus IFL (10.6 months versus 6.4 months).

Neither Avastin nor Erbitux were used with the present standard of care, which is FOLFOX (oxaliplatin /5FU/ leucovorin). Eloxatin (oxaliplatin), one of the components of FOLFOX, was approved by the FDA in 2002. A clinical trial led by the North Central Cancer Treatment Group (NCCTG) FOLFOX led to an increase in survival when compared to IFL (19.5 months versus 14.8 months).

For references go to www.researchadvocacy.org

Genetic Discrimination... Are you concerned????

Issues

Research has yielded many promising discoveries in recent years including the mapping of the Human Genome. These discoveries make it imperative that policies keep up with scientific advances in order to protect the use of information while not stalling future research. Last year, the Senate Health, Education, Labor and Pen-

sions Committee (HELP) reached a bipartisan agreement on a federal bill prohibiting genetic discrimination. The Nondiscrimination Act of 2003 (S1053) provides protection against discrimination in insurance practices and misuse of genetic information in the workplace. The House counterpart of the

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**Genetic Discrimination...
Are you concerned????**

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Senate bill is HR1910 and provides for more enforcement.

While many states have some form of legislation preventing abuse of genetic information these state laws vary in scope. For more information about state leg-

islation visit The National Human Genome Research Institute web site www.genome.gov

If you are interested in supporting this legislation, please contact your congressional representative to voice your opinion. Timing is of the essence as this window of opportunity may pass soon. To contact Congress visit www.congress.gov

**Important Research Question
Still Unanswered**

Issues in Research

In 1998 Herceptin, the first monoclonal antibody proven to be effective in treating women who had breast tumors that were HER2 receptor positive, was approved by the FDA for use in the metastatic breast cancer setting. The question immediately asked was, "Is Herceptin safe and effective in the adjuvant setting?" Here is the status of the three large randomized Phase III clinical trials that began in 2000 and 2001 that are addressing this question:

Group	Study Title	Enrollment Started	Planned Accrual	Progress
The Breast Cancer International Research Group (BCIRG) - 006 trial	Randomized Study of Adjuvant Doxorubicin, Cyclophosphamide, and Docetaxel With or Without Trastuzumab (Herceptin) Versus Trastuzumab, Docetaxel, and Either Carboplatin or Cisplatin in Women With HER2-neu-Expressing Node-Positive or High-Risk Node-Negative Operable Breast Cancer	Second half of 2001	3150 patients	Planned accrual is complete
National Surgical Breast and Bowel Project (NSABP) trial B-31	Randomized Study of Doxorubicin and Cyclophosphamide Followed by Paclitaxel With or Without Trastuzumab (Herceptin) in Women with Node-Positive Breast Cancer That Overexpresses HER2	Early 2000	2700 patients	Accrual is predicted to be complete late in 2004 or 2005
Intergroup trial led by the North Central Cancer Treatment Group (NCCTG)	Randomized Study of Doxorubicin Plus Cyclophosphamide Followed By Paclitaxel With or Without Trastuzumab (Herceptin) in Women With HER-2-Overexpressing Node-Positive or High-Risk Node-Negative Breast Cancer	First half of 2000	3300 patients	Accrual is predicted to be complete in 2005 or 2006

We need the answer to the question of Herceptin's safety and efficacy in the adjuvant setting. Many physicians are using Herceptin in the adjuvant setting now. This is probably due to two factors: a newly diagnosed patient who is HER2+ may pressure her physicians and/or the physician may believe we have the answer. We all want new treatments to move into the clinic quickly and waiting for years to get the answers to clinical trial questions is frustrating. However, we still do not know about the use of Herceptin in the adjuvant setting. Please keep NSABP B-31 and the NCCTG N9831 in mind when you speak to patients, caregivers or other advocates.

Calendar-What is Research Advocacy Network Doing?

March 2004

Sun	Mon	Tue	Wed	Thu	Fri	Sat
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

April 2004

Sun	Mon	Tue	Wed	Thu	Fri	Sat
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

Network News

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The newsletter is currently published monthly and includes articles on advocacy, research results and activities.

Research Advocacy Network

Advancing Patient-Focused Research

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Research Advocacy Network Activities

- **March 11** UCSF SPORE External Advisory Board (Invited representative)
- **March 13** Komen St. Louis Affiliate/Siteman Cancer Center Research Advocacy Symposium, St. Louis, MO (Public invited)
- **March 18** Genomic and Cancer Care Advocacy Workshop, Washington, DC (Invited representatives)
- **March 24-28** Intercultural Cancer Council Biennial Symposium, Washington, DC (Public Invited, registration info at <http://iccnetwork.org/symposium/>)
- **March 27** AACR Public Forum (Public invited)
- **March 28-31** American Association of Cancer Research, Orlando, FL
- **April 13-15** North Central Cancer Treatment Group (NCCTG) Patient Advocate representatives

**Research Advocacy
Network
Phone & Fax Number
877-276-2187**

Additions to

<http://www.researchadvocacy.org>

Check out the addition of ADVOCATE OPPORTUNITIES on the Research Advocacy Network website <http://www.researchadvocacy.org/Adv%20Opps.html>. This listing presents opportunities and contact information for research advocates to become involved in programs. Currently the list includes information about the FDA Patient Consultant Program, NCI Director's Consumer Liaison Group, NCI Consumer Advocates in Research and Related Activities, Eastern Cooperative Oncology Group, North Central Cancer Treatment Group and more. Other programs are added as information is received and opportunities are identified.

Research Advocacy Network is YOUR network. A part of our primary mission is to serve and support research advocates and in order to do that we want to hear from you. Please help us by going to <http://www.researchadvocacy.org/form.html> and completing the survey. If you prefer to have a print copy that you can fax back to us, just let us know via email to info@researchadvocacy.org or call 877-276-2187.

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