Oncology Issues

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Pharmaceutical Update

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Pharmaceutical Update

Clinical trials continue to demonstrate that Ethyol® (amifostine) protects healthy cells from the damaging effects of chemotherapy and radiation without interfering with antitumor efficacy. A randomized trial conducted by the EORTC Head and Neck Cancer Cooperative Group showed that Ethyol given to patients prior to receiving cisplatin for advanced head and neck cancer had a protective effect on renal function as well as protecting against neurologic and bone marrow toxicity. Nepro-, neuro-, and ototoxicity associated with cumulative doses of cisplatin can preclude the administration of full therapeutic doses. In the EORTC trial, patients receiving Ethyol (740 mg/m^2) as well as cisplatin had an overall response rate of 66 percent, including four complete remissions, which compared favorably with the control group. Ethyol's manufacturer, US Bioscience, expects formal FDA approval within the next month or two. (Note: no AWP is available yet, but the drug sells for $250 per vial in Europe.)

NeuTrexin. Since its FDA approval in 1993, Neutrexin (TMTX; trimetrexate) has been indicated as an alternative therapy for the treatment of *pneumoncystis carinii* pneumonia (PCP, the most common life-threatening AIDS infection) in patients who are intolerant of, or refractory to, first line TMP-SMX therapy. NeuTrexin is now being studied for use in non-AIDS cancer patients. A multi-institutional phase II trial of sequential NeuTrexin, FU (5-fluoracil) and LCV (leucovorin) in previously untreated patients with advanced colorectal cancer indicated a response rate (including more than 10 percent complete remissions) that investigators believe is unusual in this type of cancer. They are optimistic that NeuTrexin represents a successful new breed of nonclassical antifolates when combined with cytoprotective agents that shield healthy cells. (AWP is $43.66 per vial x 50 per package.)

FDA: SLOW ON THE DRAW

A nationwide poll of oncologists regarding their views about Food and Drug Administration (FDA) regulation demonstrates that the government agency has become an obstacle to the effective treatment of cancer. The telephone poll of 160 oncologists, conducted by the Competitive Enterprise Institute (CEI) in July 1995, revealed that three-quarters of the physicians believe that FDA's approval process is too slow. One in five had an unfavorable opinion of FDA. Among other findings:

- Oncologists were evenly split on whether the agency aids or hinders their use of new therapies and on whether lives are lost during the approval process.
- Nearly two-thirds believe FDA has hurt their ability to give the best possible care to a patient on at least one occasion. Greater than one in ten believes this has happened frequently.
- Three-quarters believe that the public fails to understand the human cost of FDA approval delays.
- Three-quarters oppose FDA restrictions on off-label information, and 60 percent believe this makes their job harder.
- More than 60 percent favor a change in law to make unapproved therapies available to physicians.

CEI is a nonprofit, nonpartisan public policy group, based in Washington, D.C., dedicated to the principles of free markets and limited government. For more information about the survey, contact CEI at (202) 331-1010.

INTO THE YEAR 2000

In a 182-page report chronicling the critical importance of research-intensive industries to the U.S. economy and society, the conclusion is that even with major changes in the policy environment, the expansion of the pharmaceutical industry will be close to 5 percent per year. This growth will be almost twice that of the economy as a whole. According to the report, released by the Institute for the Future, biotechnology is an essential part of the pharmaceutical industry's ongoing effort to discover and develop new medicines. "The flow of new products from the biopharmaceutical industry and the expansion of middle-class consumer markets around the world should provide the means to a healthy underlying real growth rate for the pharmaceutical industry in the next decade."

"The Future of America's Research-Intensive Industries" was released by the Institute for the Future, an independent nonprofit research group based in Menlo Park, Calif. The publication examines eight research-intensive industries: aerospace, chemicals, communications equipment, computers and office equipment, pharmaceuticals and biotechnology, scientific instruments, semiconductors and electronic components, and software. Call (415) 854-6322 for more information.

THE EUROPEAN CANCER CONFERENCE

Leading clinical and research oncologists and specialist cancer nurses from around the world converged on Paris for one of the year's most significant events in oncology—ECCO 8, the European Cancer Conference held October 29–November 2, 1995.

"The huge differences in out-

comes for patients with the same type of cancer living in different parts of the EU [European Union] is a matter of grave concern," said presenter Prof. Harry Bartelink of the Netherlands Cancer Institute in Amsterdam. "While resources and treatment are excellent in some parts of the EU, in others they tend to be failing. We need to consider why this happens and how the situation can be improved."

Bartelink noted that differences in outcomes were not acceptable. "In some clinics, recurrences of breast cancer after primary treatment occur in only 4 percent of patients. In others this figure is as high as 35 percent. Cooperation and exchange of ideas and experiences between member states of the EU are vital if we are to tackle this problem," he said.

Other presenters also highlighted differences in cancer outcomes that occur across Europe. In Switzerland, for example, more patients survive after a diagnosis of cancer than in Denmark and Scotland, said Harry Burns, M.D., a Scottish surgeon. The Cancer Outcomes Group of the European Organization for Research and Treatment of Cancer has been set up to explore these variations in outcome in a European context.

According to the European study, Eurocare, cancers amenable to cytotoxic treatment, such as cancer of the testis and Hodgkin's disease, show fairly similar high levels of survival. However, for cancer of the breast, large bowel, and stomach, for which the stage of disease at treatment is a major determinant of survival, there are substantial differences among populations. Eurocare reported on survival of almost 800,000 patients with cancer diagnosed during 1978-1985 in eleven European countries. ■