

Investigational Drug Boosts Pancreatic Ca Survival

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HOLLYWOOD, FLA. — Pairing the biologic drug erlotinib with gemcitabine, the standard agent for treating pancreatic cancer, has led to the first advance in pancreatic cancer treatment in a decade: a modest but statistically significant improvement in patient survival in a phase III trial.

"This is a difficult disease to treat, and

a lot of other studies [using different agents] have been negative, so it's a start," Malcolm J. Moore, M.D., said at a symposium on gastrointestinal cancers sponsored by the American Society of Clinical Oncology.

"This is the first time that dual therapy has improved survival. Erlotinib had a small impact on overall survival, but it's a proof of concept that targeted therapy may have benefit for this disease," commented Robert A. Wolff, M.D., an oncologist who

specializes in pancreatic cancer at the M.D. Anderson Cancer Center in Houston.

"What we'll start to see is true combination therapy, with other cytotoxic drugs added to gemcitabine plus targeted drugs on top of that. It's clear that no single targeted drug will be enough, so we'll combine targeted treatments," Dr. Wolff said.

Erlotinib (Tarceva), an oral, small molecule inhibitor of the epidermal growth factor receptor, received Food and Drug Administration approval in November

2004 as a single agent for treating refractory, advanced, or metastatic small cell lung cancer. The current study received support from the three companies that are jointly developing Tarceva—Genentech, OSI Pharmaceuticals, and Roche—but the primary organizer of the study was the National Cancer Institute of Canada. On the basis of the new results, OSI plans to file for a supplemental indication for pancreatic cancer with the FDA during the first half of this year.

The multicenter study enrolled patients with advanced pancreatic adenocarcinoma who had not been previously treated. All patients received a standard regimen of an intravenous infusion of 1 g/m² gemcitabine weekly for 7 out of the first 8 weeks, and then for 3 out of the subsequent 4 weeks. Patients were randomized to treatment with either 100 mg erlotinib daily or placebo. (Because of a slight change in the treatment protocol late in

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DR. MOORE

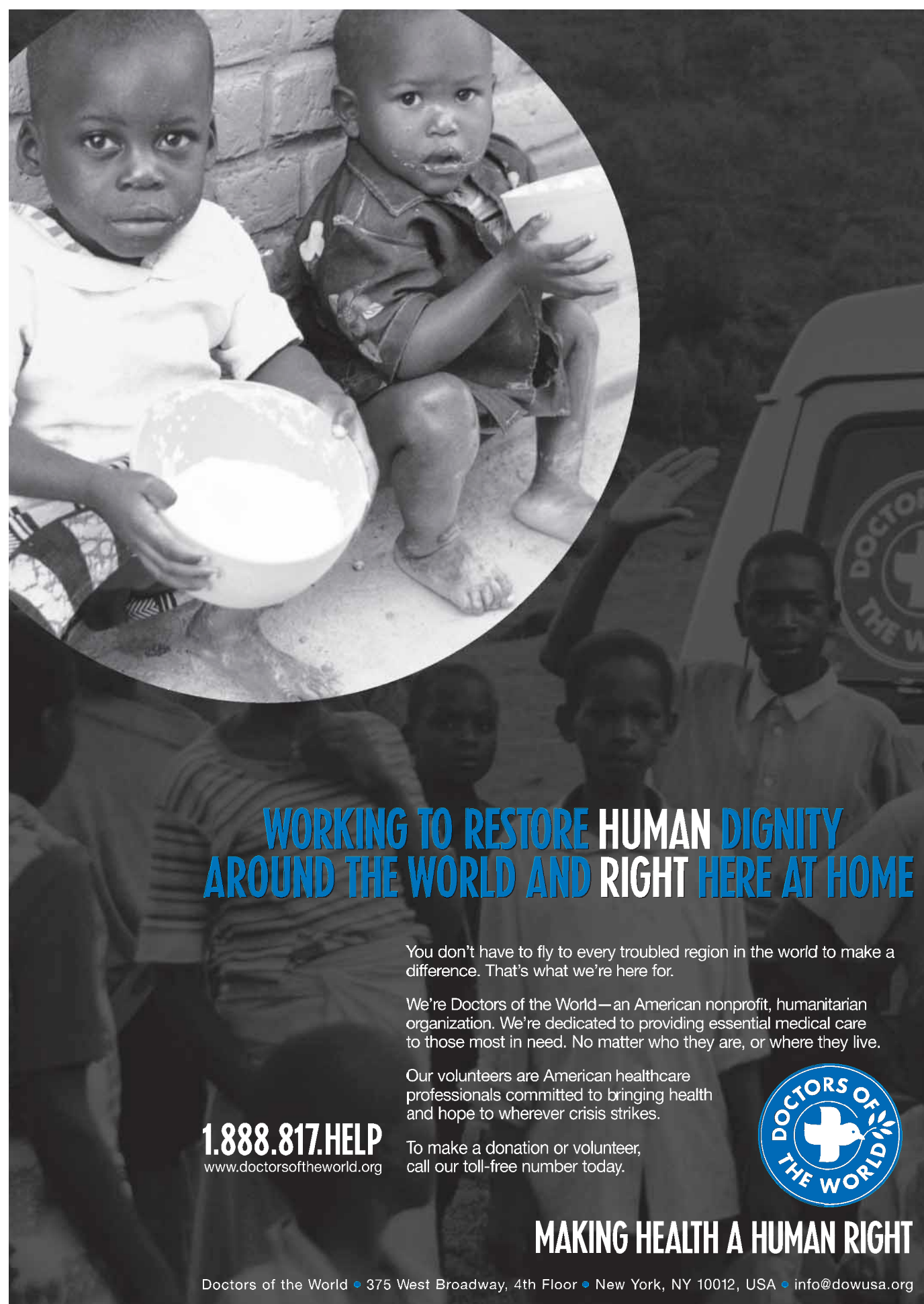
the study, about 25 of the 285 patients in the erlotinib arm received 150 mg/day.)

The study's primary end point was overall survival. The time to median survival was 5.91 months in the placebo group, compared with 6.37 months in the erlotinib group, an average gain in median survival of about 14 days. Patients treated with erlotinib had a 19% better rate of overall survival, and a 24% higher rate of progression-free survival rate compared with placebo, reported Dr. Moore, director of the drug development program at the Ontario Cancer Institute in Toronto, and professor of medicine and pharmacology at the University of Toronto.

The pattern of survival was what would be expected for patients with pancreatic cancer: A large fraction of patients progressed early and died quickly. Patients who survived the first few months after treatment tended to show a better response to erlotinib, Dr. Moore said at the symposium, also sponsored by the American Gastroenterological Association, the American Society for Therapeutic Radiation and Oncology, and the Society of Surgical Oncology.

Modest increases in adverse effects, specifically higher rates of rash and diarrhea, were seen with erlotinib but did not affect quality of life, Dr. Moore said.

A major issue in the potential use of erlotinib will be its hefty price tag, especially given its modest incremental benefit. In this study, overall survival at the end of 1 year of treatment was 17% with gemcitabine alone and 24% with both drugs. The average wholesale price for a single, 100-mg pill of erlotinib, the primary daily dosage used in the current study, is \$74.29, which works out to more than \$27,000 per year.



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