# Aspirin and Esomeprazole Appear Safe for Barrett's

BY FRAN LOWRY
*Orlando Bureau*

ORLANDO — Early findings from the Aspirin Esomeprazole Chemoprevention Trial indicate that therapy with aspirin and esomeprazole is safe and well tolerated for preventing the progression of Barrett's esophagus to adenocarcinoma.

Since the start of the randomized Aspirin Esomeprazole Chemoprevention Trial (AspECT) in September 2005, 1,192 (83%) of the 1,436 patients have remained on their medication, and just 33 adverse events have been reported, said the study's lead investigator Dr. Janusz Jankowski, professor of medicine, Oxford University (England), at a meeting on gastrointestinal cancers sponsored by the American Society of Clinical Oncology.

AspECT is an ambitious, 10-year clinical trial being conducted in the United Kingdom. The investigators are still recruiting to meet their goal of 3,000 patients. The trial's primary aim is to determine whether treatment with the proton pump inhibitor esomeprazole (Nexium, AstraZeneca) and aspirin can stop Barrett's metaplasia from progressing to adenocarcinoma.

The investigators are also trying to determine whether this therapy will prevent or reduce myocardial infarction.

The United Kingdom is fertile ground for such a study, Dr. Jankowski said at the symposium, also sponsored by the AGA Institute, the American Society for Therapeutic Radiology and Oncology, and the Society of Surgical Oncology.

"The U.K. has the highest incidence of esophageal adenocarcinoma in the world—up to four times greater than that of other countries in Europe. Barrett's metaplasia is twice as common in the U.K. as it is in the United States," he said in an interview.

Being able to show that aspirin "is in-

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# Tenofovir Beats Adefovir at Hep B Viral Suppression

BOSTON — Tenofovir suppresses viral load more rapidly and effectively than adefovir does in patients with HBe antigen–negative chronic hepatitis B, Dr. Patrick Marcellin reported at the annual meeting of the American Association for the Study of Liver Diseases.

Although both patient groups experienced a rapid decline in viral load by week 4 of the 48-week trial, those taking tenofovir experienced a steeper decline and a higher response rate, and the response was maintained, said Dr. Marcellin of the Hospital Beaujon, Clichy, France.

In the phase III trial, 375 patients with chronic hepatitis B infection were randomized to either 300 mg/day tenofovir or 10 mg/day adefovir. The primary end points were suppression of viral DNA to below 400 copies/mL and reduction of at least 2 points in the Knodell necroinflammatory score without worsening of fibrosis.

The patients' mean age was 44 years, and their mean necroinflammation score was 8. Twenty percent had cirrhosis. At baseline, mean hepatitis B virus RNA levels were about 7 $\log_{10}$ c/mL.

Both groups achieved rapid suppression of hepatitis B virus DNA, with the majority of responsive patients doing so by week 4. By week 48, however, response differences emerged. Significantly more tenofovir-treated patients than adefovir-treated patients achieved viral loads below 400 copies/mL (93% versus 63%, respectively).

There was no significant difference in histologic response between the two groups: 72% treated with tenofovir improved, versus 69% treated with adefovir. But there was a significant difference in the percentage of patients who achieved both virologic and histologic response: 71% of the tenofovir group, versus 49% of the adefovir group.

At week 48, the ALT level was normal in 77% of both groups. The incidence of ALT flare was about 1% in each group. There were no significant differences in amylase, lipase, or creatinine levels. Regarding drug resistance, none of the tenofovir-treated patients developed resistant mutations.

The phase III study was sponsored by Gilead Sciences Inc., Durham, N.C., the company that manufactures tenofovir. Dr. Marcellin disclosed he has a financial relationship with Gilead Sciences.

**—Michele G. Sullivan**