

news release

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ONE WEEK NEXIUM® AS EFFECTIVE AS FOUR WEEK OMEPRAZOLE IN *H. PYLORI* ERADICATION AND ULCER HEALING

24 May 2000 -- London -- A new approach to *Helicobacter pylori* (*H. pylori*) treatment has emerged from promising data^{1,2} presented today at the Digestive Disease Week. Data suggest that use of seven-day triple therapy Nexium[®] (*esomeprazole*), the first proton pump inhibitor (PPI) to demonstrate clinical superiority to gold standard *omeprazole*, may effectively eradicate *H. pylori* and heal a duodenal ulcer, without PPI monotherapy. Use of Nexium[®] triple-therapy reduces the four-week treatment period for patients with *H. pylori*-associated duodenal ulcer to just one week. Nexium[®] is approved for use in Sweden.

Results of two multicentre, 448-patient and 446-patient trials, ^{1,2} suggest that 20 mg of Nexium[®], in seven day triple-therapy with standard antibiotics *amoxicillin* and *clarithromycin*, effectively eradicates *H. pylori* in 90 percent of patients (CI 85-94% intent-to-treat), exceeding the recommended target in the European guidelines, the Maastricht Consensus. Furthermore, use of seven-day Nexium[®] triple-therapy heals associated duodenal ulcers in over 90 percent of patients (CI 87-97% intent-to-treat; CI 90-97% per-protocol), eliminating the need for subsequent therapy in these patients.² Seven-day *omeprazole* triple-therapy, plus three-week *omeprazole* follow-up therapy, resulted in similar efficacy to seven-day Nexium[®] triple-therapy alone.

Professor Zsolt Tulassay, Semmelweis University Faculty of Medicine, Second Department of Medicine, Budapest, Hungary, said: "Patients and physicians could potentially benefit from a reduced treatment period, greater predictability of response and effective eradication of *H. pylori* and associated duodenal ulcer healing."

Nexium[®] triple-therapy displayed a good safety profile and was well-tolerated; the adverse effects noted were those commonly associated with PPI-antibiotic combinations.



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Between 30 to 60 percent of people in Europe, North America and Australia, harbour *H. pylori* in their stomach.³ *H. pylori* infection rates can reach 90 percent in other regions of the world.⁴ This spiral shaped bacterium causes a wide range of gastrointestinal diseases, including duodenal ulcer, gastric ulcer and dyspepsia (abdominal pain severe enough for the sufferer to seek medical advice). *H. pylori* has also been associated as a precursor to gastric cancer.⁵

Nexium® was approved by the Swedish Medical Product Agency in March of this year. The Swedish agency will act as rapporteur for the European Mutual Recognition Procedure to obtain approval of Nexium® in 14 other member states in the EU, with launches in a number of these countries anticipated before the end of 2000. Nexium® is also awaiting approval in the USA (launch expected early 2001), and in other markets. Nexium® triple-therapy is the only PPI-based regimen fully documented and approved for the healing of *H. pylori-associated* duodenal ulcer, without follow-up PPI monotherapy.

AstraZeneca is a major international healthcare business engaged in the research, development, manufacture and marketing of ethical (prescription) pharmaceuticals and the supply of healthcare services. It is one of the top five pharmaceutical companies in the world with healthcare sales of over \$15 billion and leading positions in sales of gastrointestinal, oncology, anaesthesia including pain management, cardiovascular, central nervous system (CNS) and respiratory products.

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This press release contains forward-looking statements, which reflect AstraZeneca's current expectation regarding future events. The forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors, including the successful and timely completion of clinical studies, the uncertainties related to the regulatory process and the commercialisation of the drug thereafter. Investors should consult AstraZeneca's ongoing quarterly filings and annual reports for additional information on risks and uncertainties relating to these forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. AstraZeneca disclaims any obligation to update these forward-looking statements.

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References

- 1. Van Zanten S et.al. Seven day triple therapy with esomeprazole, amoxicillin and clarithromycin for *H. pylori* eradication in duodenal ulcer disease. Abstract / Study No 19. Gastroenterology 2000; 118: 2694, A503
- 2. Tulassay Z et.al. Seven day treatment with esomeprazole-based triple therapy eradicates H. pylori and heals patients with duodenal ulcer disease. Abstract / Study No 20. Gastroenterology 2000; 118: 2691, A502

 3. Kumar P, Clark M, eds. Clinical Medicine 4th edition. London: WB Saunders,
- 1998:236.
- 4. Crespi M, Citarda F. H. pylori and gastric cancer: what is the real risk? Gastroenterologist 1998; 6(10): 16-20.
- 5. Alexander. Association of *H. pylori* infection with gastric cancer. Mil Med. 2000; 165(1): 21-7.