

**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG****Novartis launches Prevacid®24HR over-the-counter for full 24-hour frequent heartburn treatment**

- *Prevacid®24HR prevents acid production that causes frequent heartburn pain for a full 24 hours with one pill a day*
- *Prevacid®24HR provides America's 50 million frequent heartburn sufferers<sup>1</sup> with convenient and easy accessibility to this effective heartburn treatment*
- *First new over-the-counter treatment for frequent heartburn sufferers in six years*

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**Basel, November 12, 2009** — Novartis announced the availability of Prevacid®24HR (lansoprazole delayed-release capsules 15 mg/acid reducer) over-the-counter in pharmacies and retail stores across the US to treat frequent heartburn. Prevacid®24HR received US Food and Drug Administration (FDA) approval in May 2009. It is the first and only over-the-counter (OTC) Proton Pump Inhibitor (PPI) for the treatment of frequent heartburn in its original formulation.

"It is well known that Americans are taking more ownership of their health-care decisions. The launch of Prevacid®24HR for the treatment of frequent heartburn is a milestone in the over-the-counter medicine category, expanding the treatment choices for the millions of adults who suffer from frequent heartburn," said Dirk Van de Put, Global Head, Over the Counter Business Unit, Novartis Consumer Health. "We're looking forward to providing frequent heartburn sufferers with broad access to this very effective treatment and expect the launch to drive strong incremental growth for the OTC Digestive Health category."

Prevacid® (lansoprazole)<sup>2</sup> was one of the most prescribed acid reducer brands in the US over the last decade<sup>3</sup> based on IMS Data. The same medicine in Prevacid is now available over-the-counter in Prevacid®24HR for the treatment of frequent heartburn. Frequent heartburn is defined as heartburn that occurs two or more days per week.

Prevacid®24HR is clinically proven to work for a full 24 hours, both day and night. It is the only PPI approved for OTC treatment of frequent heartburn that contains the active ingredient lansoprazole. Starting today, Prevacid®24HR is expected to be available in more than 100,000 pharmacies, drug stores, supermarkets, mass merchandisers and other retail locations throughout the US.

**Prevacid®24HR is clinically proven to treat frequent heartburn**

Prevacid®24HR prevents acid production that causes frequent heartburn pain for a full 24 hours, with one pill a day. Clinical study data shows that Prevacid®24HR provides frequent heartburn sufferers more heartburn-free days and nights than placebo<sup>4,5</sup>. Prevacid®24HR starts working early to treat frequent heartburn and maintains its

effectiveness for the full 14-day course of treatment. In two clinical trials, 88% of people who used Prevacid®24HR for frequent heartburn were satisfied<sup>6</sup>.

In addition to Prevacid®24HR, Novartis Consumer Health, Inc. has demonstrated success with switching other prescription products over the counter, enabling more consumers to get access to the medicines they need, while continuing to build the brands. Three of the company's biggest and most successful global switches come from the Pharmaceuticals Division of Novartis AG – Voltaren®, Lamisil® and Nicotinell® and account for 30 percent of Novartis Consumer Health global sales.

### **Frequent heartburn significantly affects sufferers' quality of life**

While frequent heartburn is a common condition, its impact on sufferers may be underestimated. According to the *Experience of Frequent Heartburn in America, 2009*<sup>7</sup>, a national study of 1,075 frequent heartburn sufferers conducted by the Center for Health Outcomes Research & Evidence Based Medicine, LLC and United BioSource Corporation, frequent heartburn is not only painful, but can also significantly impact sufferers' quality of life. The study, conducted in consultation with leading physicians and gastroenterologists, was designed to measure and validate the quality of life impact that frequent heartburn currently can have on sufferers. It found that frequent heartburn can affect sufferers' ability to get a good night's sleep, be productive at work, have positive personal relationships and enjoy social activities. The study also showed that those with more severe frequent heartburn pain can experience a greater impact on their quality of life.

"Until now, frequent heartburn has been largely misunderstood in America. The data from this study confirms how frequent heartburn affects my patients' daily lives – it can interrupt sufferers' work, social activities and a full night's sleep," said Dr. Brian Fennerty, practicing gastroenterologist and professor of Medicine in the Division of Gastroenterology at Oregon Health & Science University in Portland, Oregon. "The over-the-counter availability of a proven molecule like lansoprazole provides choice and options to the millions of frequent heartburn sufferers and empowers them to treat their symptoms."

The study, which was funded by Novartis Consumer Health, Inc. revealed that<sup>7</sup>:

- About 75% of frequent heartburn sufferers experienced some sleep problems as a result of their heartburn – either problems falling asleep or staying asleep.
- Living with frequent heartburn pain can affect personal relationships, including social activities with family and friends, quality time with children and spouses, and even sexual relationships.
- For 52% of sufferers, discomfort from frequent heartburn has some impact on their work, including their ability to focus in meetings and their overall ability to be productive.

The study also found that reducing the frequency and severity of frequent heartburn pain could result in significant improvements in a sufferer's mood, relationships with family, productivity at work, diet and enjoyment of social activities<sup>7</sup>. Additional results of the study are available at [www.Prevacid24HR.com](http://www.Prevacid24HR.com).

As part of the launch of Prevacid®24HR, Novartis Consumer Health is partnering with Dr. Fennerty and MSN.com Lifestyle Expert Kelley Moore to educate the public about frequent heartburn and motivate them to take action. Through the Heartburn Action Plan, Dr. Fennerty and Ms. Moore will share treatment options and lifestyle tips that will help empower frequent heartburn sufferers to treat their symptoms. Log on to [www.HeartburnActionPlan.com](http://www.HeartburnActionPlan.com) for more information.

### **About Frequent Heartburn**

More than 50 million American adults suffer from frequent heartburn,<sup>1</sup> which is defined as heartburn occurring two or more days per week. Frequent heartburn is a result of the backing up of stomach acid into the esophagus. Typically the lower esophageal sphincter muscle opens to allow food to pass, but then quickly closes. However, in frequent heartburn sufferers, the muscle relaxes and allows food and acid from the stomach to travel back up into the esophagus. As a result, sufferers often have a burning sensation in the chest and/or throat, a sour or bitter taste in the mouth, difficulty swallowing, chronic coughing and wheezing or other asthma-like symptoms. These symptoms of frequent heartburn can become worse when one is lying down or bending over.

### **About Prevacid®24HR**

Prevacid®24HR is now available over-the-counter to treat frequent heartburn for a full 24 hours with one pill a day. It received US Food and Drug Administration (FDA) approval in May 2009. It is the first and only over-the-counter PPI for the treatment of frequent heartburn in its original formulation.

Prevacid®24HR is clinically proven to work for a full 24 hours, both day and night. Although some people get complete relief of symptoms within 24 hours, it may take one to four days for full effect. Consumers should use Prevacid®24HR as directed for 14 days to treat their frequent heartburn and may take one 14-day course of treatment every four months, or as directed by their doctor. If their heartburn continues or worsens, they should stop use and ask a doctor.

Prevacid®24HR is expected to be available in more than 100,000 retail store locations nationwide, starting at an average retail price of \$11.99.

For more information about Prevacid®24HR, including instructions for use, visit [www.Prevacid24HR.com](http://www.Prevacid24HR.com).

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as “look forward to,” “expect,” “expected,” “can,” “could,” “will,” “may,” or similar expressions, or by express or implied discussions regarding the potential date on which Prevacid®24HR will be available for sale over-the-counter, the extent of the distribution of Prevacid®24HR, or regarding potential future revenues from Prevacid®24HR. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Prevacid®24HR to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Prevacid®24HR will be available for sale over-the-counter on any particular date. Nor can there be any guarantee regarding the extent of the distribution of Prevacid®24HR, or that Prevacid®24HR will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding Prevacid®24HR could be affected by, among other things, unexpected difficulties in manufacturing or distribution; competition in general; government, industry and general public pricing pressures; unexpected regulatory actions or government regulation generally; the impact that the foregoing factors could have on the values attributed to the Novartis Group’s assets and liabilities as recorded in the Group’s consolidated balance sheet, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

## About Novartis

Novartis provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in each of these areas. In 2008, the Group's continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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## References

- 1 National Heartburn Alliance: [http://www.heartburnalliance.org/heartburn\\_assessment.php](http://www.heartburnalliance.org/heartburn_assessment.php)
- 2 Prevacid® is a registered trademark of Takeda Pharmaceuticals North America, Inc., and is used under license by Takeda Pharmaceuticals North America, Inc.
- 3 Based on IMS Data of the total number of Prevacid® prescriptions from 1998 – 2008
- 4 Peura, DA et al. *Aliment Pharmacol Ther.* 2009; 30:459-468
- 5 Kushner PR, et al. *Postgrad Med.* 2009; 121(4):67-75
- 6 Novartis Consumer Health, Inc. Data on file.
- 7 "The Experience of Frequent Heartburn in America, 2009" Research conducted by the Center for Health Outcomes Research & Evidence Based Medicine, LLC and United BioSource Corporation

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