

**Visanne® is the first oral treatment approved in more than 10 years for  
Canadian women with endometriosis**

*~ Provides women with the first approved long-term, oral treatment option to relieve debilitating pelvic pain from endometriosis ~*

**Toronto, ON – November 29, 2011** – There is now relief for Canadian women living with the pelvic pain associated with endometriosis. The symptoms of endometriosis, including severe menstrual cramps, painful intercourse, painful urination or bowel movements, and lower back or abdominal pain, take a toll on a woman’s emotional health and overall quality of life. Bayer HealthCare announced that Visanne® (2 mg dienogest tablets) was approved by Health Canada for the management of pelvic pain associated with endometriosis. It is the first long-term, oral, progestin-only regimen specifically developed for women with endometriosis in more than 10 years.<sup>1</sup>

“Once diagnosed, endometriosis patients must use a treatment on a daily basis to cope with the immense pain of the disease,” said Dr. Sony Singh, Director of Minimally Invasive Gynecology, Department of Obstetrics and Gynecology, University of Ottawa. “Visanne is an important management option for patients with the disease, as it is proven to relieve the chronic, debilitating pelvic pain caused by endometriosis including menstrual pain and pain during sexual intercourse. This is the first new treatment in more than a decade to help these women, which is encouraging.”

Visanne® has been shown to provide effective pain relief in women with endometriosis, as clinical studies of up to 15 months duration, have proven that Visanne® is effective at relieving pelvic pain.<sup>2</sup> Visanne® contains a novel progestin called dienogest, which suppresses the effects of estradiol on endometrial tissue and effectively reduces pelvic pain.<sup>3</sup>

### **The Impact of Endometriosis**

Endometriosis is the growth of tissue, similar to the kind that lines the uterus every month, elsewhere in the abdomen. This excess tissue responds to the monthly menstrual cycle and when the tissue breaks down, it can lead to inflammation, causing pain. Common sites for endometrial growth are the ovaries, on the uterus and behind the uterus.<sup>4</sup> The condition affects approximately 5 - 10 per cent of women of reproductive age.<sup>5</sup> Pain associated with endometriosis can be excruciating and debilitating and is often the most difficult symptom for women with the disease.<sup>6</sup>

The disease can greatly impact a woman’s social, professional and personal life, and women with endometriosis often experience a higher incidence of depression and emotional distress due to the uncertainty of diagnosis, unpredictability of symptoms and living a normal life.<sup>7</sup>

### **Recognize the Symptoms**

Despite the high prevalence of endometriosis, there is a lack of general disease awareness and few women recognize the symptoms – thus causing a significant delay in diagnosis. Studies show it takes an average of three years from the time a woman has her first symptom to the time she discusses it with her doctor.<sup>8</sup> It frequently takes up to 12 years for a woman to get a confirmed diagnosis from the first time she seeks help for her symptoms.<sup>9</sup>

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“It is very common for women to live for several years with the severe pelvic pain of endometriosis before receiving an official diagnosis. This often means a delay in disease management consequently, negatively impacting their professional, social and psychological life,” said Jan Silverman, The Endometriosis Network of Toronto (TENT). “It’s important for women to learn about the symptoms of endometriosis, rather than just thinking pelvic pain is ‘normal.’ Women need to know that endometriosis is real and the pain can be treated, so it’s important for them to speak with their doctors. The availability of a new treatment is good news and a step in the right direction.”

### **The Facts on Visanne®**

Visanne® (2 mg dienogest tablets) is indicated for the management of pelvic pain associated with endometriosis. Clinical trials regarding the efficacy of Visanne® have lasted up to 15 months.<sup>10</sup>

In clinical trials, Visanne® was generally well tolerated. The most frequent side effects reported were headache, breast discomfort including breast engorgement and breast pain. Undesirable effects, such as irregular bleeding, are more common during the first months of treatment with Visanne® and subside with continued treatment.<sup>2</sup> Patients are encouraged to talk to their healthcare provider to see if Visanne® is right for them.

To learn more about endometriosis, visit [www.endometriosisinfo.ca](http://www.endometriosisinfo.ca). For more information on endometriosis support groups from TENT, visit the group’s Facebook page: <http://www.facebook.com/group.php?v=info&ref=mf&gid=301016744454>.

### **About Bayer Inc.**

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Bayer Inc. has approximately 800 employees across Canada and had sales of \$827 million CDN in 2010. Globally, the Bayer Group had sales of over 35 billion Euro in 2010. Bayer Inc. invested approximately \$36 million CDN in research and development in 2010. Worldwide, the Bayer Group spent the equivalent of over 3.1 billion Euro in 2010 in R&D. For more information, go to [www.bayer.ca](http://www.bayer.ca).

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### References:

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<sup>1</sup> Lupron Depot Canadian Product Monograph. <http://www.abbott.ca/static/content/document/LUPRON-DEPOT-ENDO-PM-23MAR10.pdf>. May 20, 2011.

<sup>2</sup> Visanne Product Monograph. 2011. Page 21.

<sup>3</sup> Visanne Product Monograph. 2011. Page 14.

<sup>4</sup> SOGC.ca. What is Endometriosis? Available at [http://www.sogc.org/health/health-endometriosis\\_e.asp](http://www.sogc.org/health/health-endometriosis_e.asp). Accessed November 1, 2011.

<sup>5</sup> Endometriosis. Infertility Awareness Association of Canada. Available at: <http://www.iaac.ca/content/endometriosis-1>. Accessed October 31, 2011.

<sup>6</sup> Hummelshoj L. Medical needs in endometriosis. Gynaecology Forum 2010;15(2):5-7.

<sup>7</sup> Kennedy S, Bergqvist A, Chapron C, D'Hooghe T, Dunselman G, Greb R, Hummelshoj L, Prentice A, Saridogan. ESHRE guideline on the diagnosis and management of endometriosis. Human Reproduction 2005;20(10):2698-2704. Also available online at: <http://guidelines.endometriosis.org/>.

<sup>8</sup> Diagnosis:  
[http://www.womenshealthmatters.com/centres/pelvic\\_health/endometriosis/diagnosis/index.html](http://www.womenshealthmatters.com/centres/pelvic_health/endometriosis/diagnosis/index.html). Accessed November 1, 2011.

<sup>9</sup> SOGC Diagnosis and Management Guidelines. Available at: <http://www.sogc.org/guidelines/documents/gui244CPG1007E.pdf>. Accessed November 1, 2011.

<sup>10</sup> Visanne Product Monograph. 2011. Page 3.