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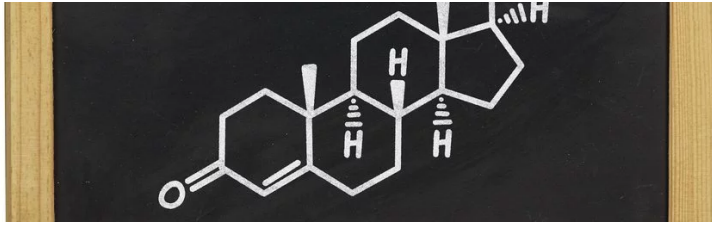
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Allergan's New Drug Application (NDA) for the marketing approval of its investigational drug ulipristal acetate has been accepted by the U.S. Food and Drug Administration (FDA) for the treatment of abnormal bleeding in women with **uterine fibroids**.

"We are eager to continue working with the FDA on the potential approval of the first, once-daily oral treatment for abnormal uterine bleeding in women with uterine fibroids," David Nicholson, PhD, Allergan's chief research and development officer, said in a **news release**.

Ulipristal acetate is marketed in Europe by **Gedeon Richter** under the trade name Esmya. In Canada, ulipristal acetate is marketed by Allergan under the trade name Fibrystal. Both are approved for the intermittent treatment of moderate to

“Uterine fibroids have a serious impact on public health, and I am hopeful ulipristal acetate will offer millions of women a new, nonsurgical treatment option that will help them manage their uterine fibroids,” said Dr. Millie A. Behera, MD, reproductive endocrinology and fertility medical director at the **Bloom Reproductive Institute** in Arizona.

Allergan expects the FDA to make a decision on ulipristal acetate in the first half of 2018, under the Prescription Drug User Fee Act.

The drug’s efficacy and safety was demonstrated in four Phase 3 clinical trials in women with uterine fibroids in Europe.

In North America, more than 500 adult women participated in two Phase 3 clinical trials (VENUS I and VENUS II). These studies had robust results showing the effectiveness and safety of ulipristal acetate in the oral treatment of uterine fibroids.

Thousands of women have been treated with ulipristal acetate for fibroids in more than 70 countries.

According to Allergan, ulipristal acetate is a selective progesterone

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Ulipristal acetate blocks the effect of progesterone on the endometrium (lining of the uterus), uterine fibroids, and the pituitary gland, which is the pea-sized body on the base of the brain that controls the functioning of endocrine glands. This will eventually cause the fibroids to shrink, become less painful, and stop heavy menstrual bleeding.

“Women with symptomatic uterine fibroids may suffer from physical and emotional distress without realizing their symptoms are caused by a treatable medical condition,” Nicholson said.

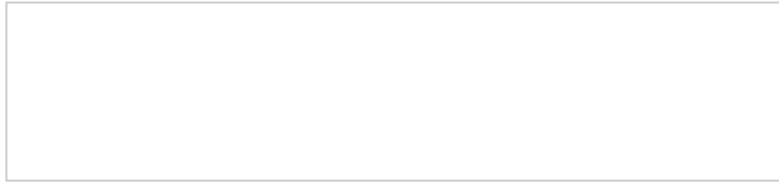
Behera added that it is “welcome news for physicians to learn about the possibility of an oral treatment option” for uterine fibroids.

According to the **Agency for Healthcare Research and Quality (AHRQ)**, it’s estimated that 26 million women of reproductive age have uterine fibroids. Women with this condition have their daily lives affected due to iron deficiency, fatigue, **pain**, along with social embarrassment.

Currently, surgery is a common approach for the treatment of this



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— One comment —



Kim says: February 17, 2018 at 7:06 AM

I was actually searching the internet for alternatives to Esmya / ulipristal. There is a worldwide advice to stop prescribing it and women that are on it, to stop. In France there are cases of liver faillure and transplantation necessary due to ulipristal...

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