



Raising Awareness of Fibromyalgia Syndrome

Press release 27 October 2008

**Severe blow for millions of Fibromyalgia Syndrome sufferers
as European Medicines Agency rejects first drug approval**

Millions of chronically ill patients across Europe have received a severe knock-back with the announcement that the European Medicines Agency has rejected the application of the first medicine, Duloxetine hydrochloride, trying to get EU approval as a treatment for Fibromyalgia Syndrome (Fibro).

Duloxetine already has approval by the American Food and Drug Administration (FDA) for the treatment of Fibro and it has been authorised by the European Medicines Agency (EMA) since December 2004 as a treatment for other conditions, including painful diabetic neuropathy and episodes of major depression.

Pharmaceutical companies Eli Lilly and Boehringer Ingelheim wanted Duloxetine to be officially indicated as a treatment for Fibro, so that they could market it for this purpose.

This change was refused, despite numerous trials concluding that the drug was safe and efficacious in reducing symptoms of Fibro and that the drug's effect on Fibro symptoms is independent of its effect on depression (*Russell et al, 2008; Arnold et al, 2005; etc*).

Fibro is a debilitating, painful chronic condition which affects between 1.2 and 2.7 million people in the UK alone. Despite an increasing body of evidence that Fibro is a real, physical condition related to Central Nervous System dysfunction, there are still medical professionals who refuse to admit the evidence and say that Fibro is not a real condition. Voluntary organisations across Europe suspect that these outdated views may have had an impact on the Duloxetine decision.

"FibroAction are disappointed to learn of the refusal to allow the clinical indications of Duloxetine to be extended to include Fibromyalgia Syndrome" said Lindsey Middlemiss, founder and chair of FibroAction. "We hope that outdated views of Fibro were not a factor in this decision and that the evidence was considered without an unfair bias. The millions of sufferers across Europe desperately need the help that a properly approved drug would bring."

The refusal is likely to perpetuate the myth that because no drugs have marketing approval in the EU for Fibromyalgia Syndrome, there are no treatments available for the condition. Because Duloxetine already has EMA authorisation, it is available on prescription if a doctor considers that it is an appropriate treatment. This is also true of many other treatments for Fibro, some of which are already widely used.

For more information see www.fibroaction.org

ENDS

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Further information:

- The Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency (EMA) made the decision on Duloxetine.
- Duloxetine would be marketed as Cymalta and Xeristar by Eli Lilly and Boehringer Ingelheim.
- **Fibromyalgia Syndrome (Fibro)** is also referred to as Fibromyalgia, FMS and FM. Fibromyalgia is pronounced Fy-bro-my-AL-gee-ah. FibroAction prefer the abbreviation, Fibro, as it is easy to pronounce, spell and remember.
- The estimate of 1.2 and 2.7 million people with Fibro in the UK is based on internationally recognised prevalence statistics of 2-4.5% of the population. The prevalence of Fibro in the UK has historically been hugely under reported.
- FibroAction (registered charity number 1125957) was set up in April 2008.
- FibroAction is an incorporated charity and as such is also a company registered in England and Wales (company number 6662336).
- FibroAction aims to educate people about Fibromyalgia Syndrome (Fibro), including people with Fibro, healthcare professionals and the general public, as well as providing support to patients.
- For more information on Fibro and FibroAction, please see the [Media Section](#) of our website:
<http://www.fibroaction.org/Pages/Media-Section.aspx>

References:

- Russell, IJ, et al. Efficacy and Safety of Duloxetine for Treatment of Fibromyalgia in Patients With or Without Major Depressive Disorder: Results From A Six-Month, Randomized, Double-Blind, Placebo-Controlled, Fixed-Dose Trial, *Pain*. 2008.
- Arnold, L, et al. A Randomized, Double-Blind, Placebo Controlled Trial of Duloxetine in the Treatment of Women with Fibromyalgia With or Without Major Depressive Disorder. *Pain*. 2005; 119 (1-3): 5-15
- Arnold, L, et al. A Double-Blind, Multicenter Trial Comparing Duloxetine with Placebo in the Treatment of Fibromyalgia Patients With or Without Major Depressive Disorder. *Arthritis Rheum* 2004; 50(9):2974-84.