A new article has been published with updated information on this subject: Huntexil hits the headlines again x

Huntexil update: EMA asks for further trial

European Medicines Agency (EMA) tells NeuroSearch a European license for Huntexil in HD requires another large trial

By Dr Ed Wild on June 06, 2011

Edited by Dr Jeff Carroll

In April, the American drug regulator told NeuroSearch it would need a further large clinical trial before its Huntington's disease symptom-control drug Huntexil would be licensed. Now the European regulator, the EMA, has said the same for European licensing.

The EMA's advice

NeuroSearch, the Danish drug company developing Huntexil, has received advice from the European Medicines Agency (EMA) about what will be required before the company can apply for a license to sell Huntexil in Europe.

Last month, the American Food and Drug Administration (FDA) had ruled that the data from NeuroSearch's existing trials - MermaiHD in Europe and HART in the USA - were not sufficient to prove the drug was safe and effective enough to be licensed in the USA.

The EMA's advice echoes that of the American regulator, with both bodies calling for a further large 'Phase III' trial of several hundred volunteers before a license can be applied for on either continent.

NeuroSearch, Huntexil and Huntington's

Huntexil is the brand name of ACR16, also known as pridopidine. Developed by Neurosearch, a Danish pharmacology company, Huntexil is a new possible treatment aimed at improving symptoms of Huntington's disease.

Huntexil's target is the movement, or 'motor' symptoms of HD. Unlike existing drugs, Huntexil isn't just aimed at damping down the involuntary movements ('chorea' and 'dystonia') but at improving overall motor function including balance and voluntary control.

NeuroSearch had hoped that data from its HART and MermaiHD trials would persuade one or both regulators to consider a license, but - though both trials showed some encouraging results - neither one met its statistically pre-defined cut-off for proving the drug effective.

Back to the drawing board?

NeuroSearch appears committed to getting Huntexil licensed and has settled on a basic design for a new Phase III trial, but hasn't yet announced where or when it'll take place.

Licensing for drugs is often a rocky road, and the process is understandably frustrating for those waiting for new treatments. Drug regulators are cautious, and rightly so - too many drugs in the past have been licensed only to be withdrawn later when harmful or even lethal side effects emerged.

Lars Madsen, Vice President of Project and Portfolio Management at NeuroSearch, told HDBuzz "We are still committed to intensively drive pridopidine all the way to the market," and said NeuroSearch will shortly "have a road map for our coming activities".

The authors have no conflicts of interest to declare. For more information about our disclosure policy see our FAQ...

Glossary

Food and Drug Administration The government regulatory authority in the US responsible for approving new drugs

clinical trial Very carefully planned experiments designed to answer specific questions about how a drug affects human beings

phase III The phase in the development of a new treatment where clinical trials are conducted using many patients, to determine whether the treatment is effective

dystonia sustained involuntary muscle contractions, a bit like chorea but lasting longer

chorea Involuntary, irregular 'fidgety' movements that are common in HD
