

Final stretch in phase IIa of clinical trial for ground-breaking Spanish drug indicated to treat paraplegic pain caused by spinal cord injuries

- **In three months, biotechnology company Neurofix will have the first results of phase IIa of NFX88 and will be able to begin phase IIb/III towards the end of the year.**

Pain caused by a spinal cord injury, commonly called neuropathic pain, **is one of the most difficult pathologies to treat in this area**. It's a condition which can cause shooting pain, a cold sensation, shocks, pins and needles, and sometimes an overwhelming burning sensation. Current treatments are inadequate, as they only cover the symptoms, and patients with paraplegia are forced to turn to drugs such as antidepressants, opiates, and painkillers. **Spanish biotechnology company Neurofix seeks to fill this gap** by developing a ground-breaking treatment which has been trialled in seven important hospitals in Spain.

NFX88 is currently in the final stretch of phase IIa of its clinical trial and is nearing the start of phase IIb/III, the final clinical milestone before its commercial registration. **This means the first efficacy results in humans will be available in the first quarter of this year**. Neurofix will then be able to apply to the EMA for designation as an orphan drug for a rare disease. Neurofix also expects to begin contact with the United States FDA (Food and Drug Administration). The goal is **to have this therapy available on the market by 2025** so it can start improving the quality of life of people who suffer from paraplegia due to spinal cord injury.

It is worth remembering that, of the over 50 drugs created by Spanish companies which are currently undergoing clinical trials, **at present only ten have reached phase III**, according to information provided by the Asebio Spanish Association of Biotechnology Companies.

How is NFX88 different to current treatments? The expression of neuronal growth factors helps reduce inflammation and repair the myelin sheath of the affected nerve cells. For the first time, patients suffering from this condition will be able to rely on a specific treatment that is not available to them today.

This therapy has been tried out in **seven medical centres throughout Spain**: the National Hospital for Paraplegics in Toledo (the coordinating centre for the trial), the Coruña University Hospital Complex (CHUAC), the Vall d'Hebron Hospital in Barcelona, the Virgen de las Nieves Hospital in Granada, the Virgen del Rocío University Hospital in Seville and private centres Institut Guttmann in Barcelona and the Los Madroños Hospital in Brunete (Madrid). Currently, manufacturing optimisation is achieved, with the end goal of creating a pharmacological treatment which is more convenient for the patients.

Dr Antonio Oliviero, trial coordinator, clinical neurologist, and head of the research team (FENNSI Group) at the National Hospital for Paraplegics in Toledo, said: **"NFX88 gives hope to patients that haven't been able to find sufficient treatment for their pain**. That is what's most important: giving them an opportunity to improve their quality of life."

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Spinal cord injuries are usually caused by trauma to the spinal column, which fractures or dislocates the vertebrae. These injuries can lead to chronic pain, called neuropathic pain. **It is estimated that this condition affects 25% of the world population**, of which between 7% and 8% are located within Europe, although some studies believe this number reaches up to 20% amongst adults. Current oral treatments of this condition reduce, on average, only 20-30% of pain intensity and have significant side effects. This translates to an **annual healthcare cost of 33 billion euros**, or 0.33% of European countries' GDP.

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Neurofix

Neurofix is a biotechnology company whose mission is to develop innovative treatments for neurological pathologies. Its most advanced product is NFX88, which is currently in the final stretch of phase IIa of its clinical study in seven important hospitals. Its goal is to treat neuropathic pain in spinal cord injury patients. Neurofix obtained the highest marks in Spain in the NEOTEC programme run by the Ministry of Economy and Competitiveness in 2017, has been awarded four Seals of Excellence by the EU in the Horizon programme, and is registered as a European SME and Innovative PYME. neurofixpharma.com

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