CASE STUDY

NBO Pharma see the immediate benefits of an integrated approach to intranasal product development with the Aptar Pharma family of services

Nanopharm

an Aptar pharma company

NANOPHARM AND APTAR PHARMA SERVICES EMPLOYED

A full-service portfolio of services has been employed to accelerate the development of a first to market liquid nasal drug delivery product containing octreotide acetate, for the treatment of Idiopathic Intracranial Hypertension [IIH].

SPECIFICALLY, THE CLIENT HAS TO DATE, UTILIZED THE FOLLOWING SERVICES:

- Nanopharm: SmartStart formulation and analytical development in parallel with supply for preclinical PK and toxicology studies through to lead candidate selection for Phase 1 clinical studies
- Aptar Pharma Services and Nanopharm: formulation optimization, analytical methods qualification, cGMP batch release and stability study
- Aptar Pharma services: CMC (chemical, manufacturing, controls), cGMP fill/finish for Phase 1 clinical trial, IND combination product regulatory support, extractable and leachables.
- Aptar Pharma: supply of VP7 multidose nasal spray pump

CONTEXT

IIH (Idiopathic Intracranial Hypertension) is a rare condition that mainly affects women in their 20s and 30s, resulting in a US and EU patient population estimated to be in excess of 50,000 people.[1]

Symptoms often mimic those of a brain tumor and if left untreated, IIH can lead to papilledema [bilateral optic nerve swelling]. It can be a progressive condition, leading to the enlargement of blind spots, visual obscuration and even loss of vision. Acute IIH can be fatal if not treated promptly as a medical emergency, while chronic IIH is generally a lifelong condition resulting in a comparatively high hospital admission rate of 38% in the US.

There are currently no drugs approved for the treatment of IIH. Two drugs are sometimes used off-label, acetazolamide (Diamox) and topiramate (Topamax), but both have significant dose-limiting side effects resulting in acetazolamide featuring a discontinuation rate of approximately 50%. In addition, there is currently no evidence-based consensus or guidance on drug management for IIH.

For extreme cases, surgery may be required to protect the optic nerve which involve a highly invasive procedure such as Shunt Placement, Optic Nerve Sheath Fenestration, Venous Sinus Stenting or a Spinal Tap (Lumbar Puncture).

NBO Pharma's objective is clear: to accelerate the development time to Clinical Trial phase for a product with orphan drug status to meet an unmet patient need.

While independent clinical studies have reported positive results from subcutaneous treatment with octreotide, three-times per day injections come with objections, particularly for patients already suffering from poor eyesight, anxiety and needle phobias.

CHALLENGES

The key challenge for NBO Pharma was to accelerate development, while remaining in line with FDA guidance to mitigate the risk of unsatisfactory filing and delayed commercialization.

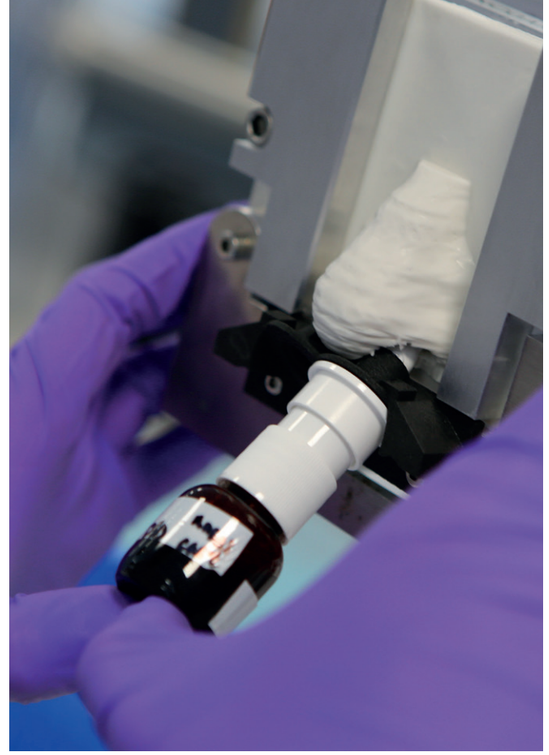
SOLUTION

Led by a dedicated manager at Nanopharm, a project team was assembled featuring specialists from the required Aptar Pharma portfolio businesses. With Nanopharm acting a single point of contact, NBO Pharma was able to benefit from a coherent and cohesive approach to the project, pulling in expertise as necessary to ensure a rapid development process while mitigating risk, minimizing cost and ensuring compliance with FDA requirements.

OUTCOME

2025 witnessed the successful completion of an IN CNS 14-day maximum tolerated dose canine toxicology study, an IN CNS 3-month canine toxicology study and an IN Phase 1 PK, dose, and safety clinical trial in 20 healthy subjects.

It is anticipated that in H2 2026, an IN Phase 2a open label 1-month safety and efficacy clinical trial in 20 IIH patients will commence, with an estimated completion in Q3 2027.



Fredric Price, Founder and CEO of NBO Pharma Inc. commented

NBO has benefitted from the seamless operations of the wider Aptar Pharma family. This 'one-stop shop' avoids inter-corporate tech transfer and political issues which in turn reduces development time, cost and risk – three business critical factors for us in our strive to progress to the next Clinical Trial phase.

CAN WE HELP YOU ACCELERATE YOUR NEXT INTRANASAL PRODUCT DEVELOPMENT?

In a world where orphan drugs, rare disease therapies and personalised treatments begin to become increasingly demanded by pharma and regulators alike, effective and efficient drug delivery systems must keep pace to continue to meet unmet patient needs.

Nasal drug delivery represents a highly effective, non-invasive method that bypasses the digestive tract and hepatic first-pass metabolism. It offers rapid systemic absorption, direct nose-to-brain targeting, and excellent patient convenience for administering medications, hormones, and emergency treatments.

But it is not without complications, and successful commercial requires specialist guidance from a supportive, expert partner. Nanopharm and the Aptar Pharma family is focused on providing highly specialized Orally Inhaled and Nasal Drug Product (OINDP) development and analytical services that accelerate the development of your drug-device combination product and help bring it to market faster.

Nanopharm applies its specialized expertise across a range of OINDP drug delivery formats and molecule types. Our specialty is developing nasal and inhaled drug delivery products for small molecules or biologics in combination with a variety of devices suitable for innovator, generic, or lifecycle management applications. To find out more visit: https://nanopharm.co.uk

For more information Call +44 (0) 1633 504 776 email: enquiries@nanopharm.co.uk visit us at www.nanopharm.co.uk

Are you developing a novel OINDP? We offer a unique multi-dimensional development process that covers preformulation & preclinical development, formulation & drug product development, as well as clinical development services. We call it SmartStart.

CLINICAL SUPPLIES MANUFACTURE & RELEASE

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email: enquiries@nanopharm.co.uk
visit us at www.nanopharm.co.uk