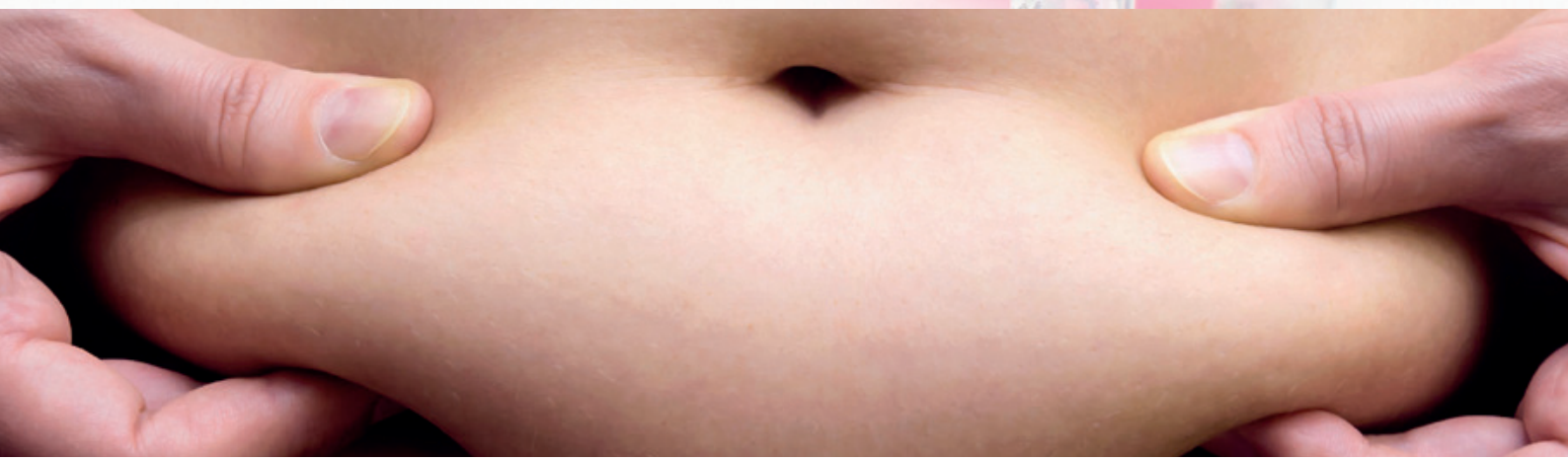
NeuroVive PHARMACEUTICAL

Newsletter

November 2016



NASH – an exciting area in NeuroVive's new business model

In the beginning of November, we could report that one of our cyclophilin inhibitors, NVP018, has shown positive preclinical results in an experimental model of the chronic and common liver condition NASH (non-alcoholic steatohepatitis). The NASH project is in line with the company's updated business strategy which includes increased and accelerated efforts in moving high potential discovery projects forward with the aim of out-licensing during the preclinical phase.

We have spoken to NeuroVive's CEO Erik Kinnman and the company's medical chief Magnus Hanson about the latest news.

We begin with asking Magnus Hansson, Chief Medical Officer at NeuroVive, a few questions.

What is NASH?

NASH is a common liver disease which for a long time was associated with an overconsumption of alcohol. This was changed in the 1980s when fat incorporation in the liver was observed also in absolute non-drinking patients and the disease was then given the name non-alcoholic steatohepatitis (NASH). A fatty liver can, in combination with inflammation, lead to permanent liver damage and the patient has an increased risk of getting serious complications such as liver cirrhosis or the development of hepatocellular cancer (HCC).

NASH and NAFLD, two names of the same disease?

No, NASH is part of a group of conditions under the umbrella term NAFLD - non-alcoholic fatty liver disease – one of the most common diseases in the world. It is estimated that 20 % of the global population suffer from NAFLD and about one-third of the population in the US. Approximately 3-5 % of Americans (approx. 15 million people) suffer from NASH, and there are currently no registered drugs for the treatment of this condition.[1)]

Why do people get a fatty liver?

There is a strong association between NASH and a variety of metabolic syndromes, e g diabetes and obesity. There is also a link between NASH and insulin resistance and glucose resistance. Most patients have no symptoms. A biopsy or tissue sample is needed to confirm the diagnosis, and this makes the disease even more difficult to detect.

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What results have you seen with your substance?

NVP018 has shown positive preclinical results in an experimental model of NASH. In addition to NVP018, we are developing a completely new class of compounds with a different mode of action that may offer complementary treatment of NASH. Here we have utilized NeuroVive's core competence in mitochondrial energy regulation with our partner company Isomerase's innovative chemistry capabilities. The results are an important step forward in the development towards out-licensing.

Over to Erik Kinnman, CEO NeuroVive:

How do you value the NASH project?

NASH has become a somewhat hidden widespread disease and we notice an increased interest for the indication. Given the huge patient population, the high unmet medical need and that it is an area which gains interest from many international actors, we see the NASH project as the one of the projects that closest in time can create great value for the company.

You mentioned a new business model in the press release – please clarify.

The new business model contains two parts. One part involves taking drugs for rare diseases (orphan indications) with high unmet medical need through clinical development and into the market ourselves. The second part deals with high potential large indication projects like NASH, where the goal is out-licensing in the preclinical phase. Mitochondrial medicine continues to be our core focus and with this specialist competence we aim to offer new treatment options to patients with unmet medical needs.

You have recently strengthened your research organization – what do you mean by that?

Our latest recruitment, the senior scientist Dr. Michele Tavecchio, will perform R&D activities related to our discovery research programs, which have become even more important in our new business model. Therefore, we decided to further secure the competence in this part of the drug development chain. Michele holds a PhD in Cancer Pharmacology from the Mario Negri Institute for Pharmacological Research in Milan where his research activities have been focused on the involvement of ciclophilin D in various aspects of metabolic diseases and cancer, which fits hand in glove with NeuroVive's project portfolio. We warmly welcome him to our team.

FACTS

The definition of fatty liver is when at least 5 % of the liver's total weight is fat. Fatty liver was for a long time associated with an overconsumption of alcohol, but this view was changed in the 1980s. Fat incorporation in the liver also in absolute non-drinking patients – in combination with inflammation – gave the disease the name non-alcoholic steatohepatitis (NASH). The overall term used for this type of fattening of the liver is non-alcoholic fatty liver disease (NAFLD).

When the patient has fibrosis and inflammation in the liver, it is defined as NASH, a condition which may develop into liver cirrhosis or hepatocellular cancer (HCC). The present data shows that NeuroVive's substance prevents fibrosis development in a well-validated experimental model of NASH.

MARKET POTENTIAL

NASH is part of a group of conditions under the umbrella term NAFLD - non-alcoholic fatty liver disease – one of the most common diseases in the world. It is estimated that 20% of the global population suffers from NAFLD and about one-third of the population in the US. There is a strong association between NASH and a variety of metabolic syndromes like diabetes and obesity. Approximately 3-5 % of Americans (approx. 15 million people) suffer from NASH and there are currently no registered drugs for the treatment of this condition.[1)] The global market is estimated to reach 15 billion USD by 2025.[2)]

1) *Vernon G. et al. Aliment Pharmacol Ther. 2011;34(3):274-85*
2) *Nature Reviews Drug Discovery, Nov 2016, Vol15 (doi:10.1038/nrd2016.188)*

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NeuroVive at Bubble & Debate

On October 5, NeuroVive's Chief Medical Officer Magnus Hansson, together with Ulf Malmqvist, operations manager at Clinical Trials Skåne and Gavyn Edmunds, research and innovation strategist at Region Skåne, participated at Bubble & Debate, an event organized by the trade association SwedenBIO on the theme "Efforts are put on Life Science on a Swedish national level. What is done in Region Skåne?"

The discussion came to focus primarily on how the different actors should work in order to make resources and necessary support functions for clinical trials available to as many people as possible. Magnus presented NeuroVive's way of performing the company's clinical development in close collaboration between academia, hospitals and other companies within life science. This model has proven to be successful both from a national and regional perspective. During the debate, it became clear how important a better co-ordination would be to increase general access to the most competent resources and enabling a time and cost effective work flow.

ABOUT NEUROVIVE

NeuroVive Pharmaceutical AB is a leader in mitochondrial medicine. The company is committed to the discovery and development of medicines that preserve mitochondrial integrity and function in areas of unmet medical need. The company's strategy is to take drugs for rare diseases through clinical development and into the market. The strategy for projects within larger indications outside the core focus area is out-licensing in the preclinical phase.

NeuroVive is listed on Nasdaq Stockholm, Sweden (ticker: NVP). The share is also traded on the OTCQX Best Market in the US (OTC: NEVPF).

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