

Newsletter

March 2023

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First Patients Screened



Spring is in full swing! During my last visit to Lund, I took a walk among both snowdrops, scilla, and the first signs of the magnolia bloom. Our FALCON study with KL1333 is also now under way, and the first patients are undergoing their mandatory screening period of 8 – 12 weeks before they can receive their first dose of KL1333.

Additional clinical sites have been activated around Europe and in the US, and they will continue to screen patients in the study's Wave 1 this spring.

In this issue of the newsletter, you will meet our new Vice President of Clinical Operations, Dag Nesse, who started working with us this February. Dag and I have worked together in the past, and I am thrilled to have him join us. With over 25 years of experience in clinical operations, Dag was instrumental in taking TARPEYO® (Calliditas) through a pivotal study to marketing application and regulatory approval. He plays a critical role at Abliva as our clinical team works to ensure the study is delivered on time and on budget with high quality data.

At the Extraordinary General Meeting on March 8, Dr. Edwin Moses was elected to Abliva's Board of Directors. Dr. Moses is known throughout the industry for his ability

to create high value biotech companies and I look forward working closely with him as we grow Abliva into a leader in the development of medicines for diseases of mitochondrial dysfunction. Read more about Edwin on page 3.

We have many important meetings and conferences to look forward to during the first half of the year. In March we have presented the company at BioStock's Investor Meeting (link at the end of the newsletter) and then attended Bio-Europe. Looking forward, we will participate in two major mitochondrial medicine meetings taking place in June: Euromit in Bologna, Italy, and UMD's Mitochondrial Medicine in Charlotte, NC, USA. Both meetings bring together researchers, doctors, patients and their families to share knowledge, create understanding of the challenges in the field, and to build and strengthen collaborations. In addition, we will have the opportunity to meet with parts of the study personnel working on the FALCON study, to further build our relationship with our talented global study team. More of Abliva's upcoming events may be found on page 4.

Wishing you a Happy Easter!

Ellen Donnelly
CEO

Abliva Recruits Vice President of Clinical Operations

BioStock Interview, February 10, 2023



Lund-based Abliva kicks off 2023 with a recruitment to strengthen the team. The biotech has appointed Dag Nesse to the position of Vice President, Clinical Operations. One of Nesse's main task will be to oversee the operational aspects of the FALCON study with lead candidate KL1333. BioStock contacted Nesse to learn more about him and his new role.

At the end of 2022, Abliva reached its main goal for the year – the initiation of the FALCON study with KL1333. The candidate, which is Abliva's lead asset, is being developed for the treatment of a group of rare diseases known as primary mitochondrial diseases. Learn more about mitochondrial disease [here](#).

Potentially registrational phase II study

The aim of the phase II FALCON study is to assess the safety and efficacy of KL1333 to improve chronic fatigue and muscle weakness in adult patients with primary mitochondrial disease. KL1333 has previously shown improvements in fatigue and muscle function in patients treated with a low dose of drug over 10 days of treatment; Abliva now seeks to confirm these early signs of efficacy in the large, global FALCON-study.

The study is a randomised, placebo-controlled and potentially registrational study which will include 120–180 patients. Abliva expects the first patient to be dosed in Q1 2023.

New VP of Clinical Operations

In a move to further strengthen its team and ensure a keen focus on clinical development, Abliva has recruited Dag Nesse as Vice President of Clinical Operations. Nesse is a life science-veteran with 25 years of experience from all stages of development, including extensive experience in the rare disease space. Highlights from his years of experience were roles as the Head of Clinical Operations at Calliditas Therapeutics and Head of Clinical Operations at Modus Therapeutics, both developing treatments for rare diseases.

As VP of Clinical Operations, Nesse will work in collaboration with Abliva's CMO Magnus Hansson on the development strategy of Abliva's two candidates, KL1333 and

NV354. He will also join the management team and contribute to the strategic direction of the company.

VP of Clinical Operations comments

BioStock contacted Dag Nesse to find out more about him and his new role at Abliva.

Dag, what attracted you to join Abliva?

"I have always had a keen interest in working with companies focused on providing treatments to groups of patients that have fallen under the radar because there are just too few of them suffering from their diseases. Many of these diseases are devastating for patients and their quality of life and have often been unprioritised – like patients suffering from mitochondrial disease.

Working in this area of rare diseases we work closely with patient advocacy groups, specialised hospitals, and clinics and dedicated research staff, all united under the same goal – to deliver high quality clinical studies that can be the basis for approval of new drugs for patients that have no treatments available to relieve their suffering.

Having the opportunity to be part of a small, dedicated and highly experienced team that focuses on rare diseases and are committed to enabling patients to live longer and better lives, is a dream job for me, and I believe that I can be part of making a difference."

What will you add to the Abliva team?

"As a leader of the Clinical Operations group I will bring my experience in drug development, operations, and quality and ensure that the data we deliver is reliable and valid and the study is delivered with the quality necessary to support regulatory approval and marketing authorisation should the study read out positive. I have experience of successfully bringing an orphan drug to market in both

the US and EU and hope to put that experience to work with KL1333.

In addition, I have worked in clinical operations across the globe, living in the US, Australia, Saudi Arabia, Sweden, Denmark, and Norway, and working in almost every corner of the earth. I think this experience will benefit Abliva as we run our global study and work with partners across the world. I am very happy to be part of this journey, delivering mitochondrial health to patients who are desperate for treatments."

What are your main goals for 2023 in your new role?

"My main focus in the first half of 2023 will be ensuring operational excellence at all levels on the KL1333 FALCON study, working with our Clinical Project Manager Fia Ence and our CMO Magnus Hansson, our CRO ICON and our clinical sites to ensure that the study is well executed and that everything is in place to allow patients to be screened, dosed and remain in the study for the duration of the 48 week study. While our primary focus is study execution, I will also be working to ensure the appropriate procedures and processes are in place at Abliva to support possible registration and marketing approval.

I am also excited to work with the management team to continue to develop the corporate strategy and find additional opportunities to grow Abliva into a globally-recognised mitochondrial disease company."



We'd love to learn a little bit more about you. What do you enjoy doing when you aren't working?

"I love to cook. I even participated in a reality cooking show in Norway, like Masterchef, which definitely put me outside my comfort zone, being on TV. My family comes from the Norwegian west coast, mainly with farms and small villages, where everything used to be made from scratch, using all parts of the animals or products. Cooking is like meditation for me, and to spend a long day in the kitchen and invite family or friends for dinner is the perfect weekend.

I also love to travel and have been in over 120 countries, either through work or privately. My goal is to, maybe, one day have visited all countries in the world. And, as a Norwegian, I definitely enjoy skiing and snowboarding."



Dr. Edwin Moses Elected New Board Member

At the Extraordinary General Meeting on March 8, Dr. Edwin Moses was elected to Abliva's Board of Directors. Dr. Moses' primary focus is on high growth businesses, with a particular expertise in drug discovery and development.

- [See the press release here](#)
- [Read more about Abliva's Board of Directors here](#)



Spreading the Word

Communicating our mission, our strategy, and our data to the external community (patients, physicians, researchers, investors) is critical as we work to build the premier company in mitochondrial medicine. Primary mitochondrial disease is an area unknown to many, so we aim to educate and inform as we work to develop therapeutics to treat these patients. Recent events have included:

BioStock Investor Meeting (Digital)

March 16, 2023.

Presentation: <https://youtu.be/6FjwP6vsk5c>

BIO-Europe Spring Digital

March 20 - 22, 2023.

Upcoming Events



Kempen Life Science Conference

Amsterdam, Netherlands

April 25 - 26, 2023



EUROMIT

Bologna, Italy.

June 11 - 15, 2023



BIO International Convention

Boston, USA.

June 5 - 8, 2023



UMDF's Mitochondrial Medicine

Charlotte, NC, USA.

June 28 - July 1, 2023