



PRESS RELEASE

Published 26-05-2020

Asarina Pharma AB (publ) Interim Report Q1 2020 released

Asarina Pharma CEO Peter Nordkild: “In April 2020 we released inconclusive topline results from our phase IIb study in PMDD. Although disappointing, these results do not invalidate our 40 years’ research into allopregnanolone and Sepranolone. Allopregnanolone remains implicated in a wide range of stress- and compulsion-related disorders, from Tourette to menstrual migraine to OCD, PTSD, compulsive gambling, addiction and more. As the endogenous compound that modulates the body’s allopregnanolone levels, our novel treatment Sepranolone remains a driving scientific and commercial force for us. Sepranolone achieved an excellent safety profile during the phase IIb PMDD study, and we continue to move ahead with our fully-funded studies for menstrual migraine and Tourette syndrome.”

FINANCIAL HIGHLIGHTS

Significant increase in R&D costs

Financial gain due to change in SEK

Solid cash position on 31 March (110.0 MSEK)

SIGNIFICANT EVENTS DURING THE FIRST QUARTER

PMDD

In April 2020 we released inconclusive topline results from our phase IIb study in PMDD. Our active Sepranolone substance performed on a par with previous study results, however, a statistically significant difference from placebo could not be demonstrated due to an unusually high placebo response. Sepranolone achieved an excellent safety profile during the study. We will no longer be developing Sepranolone for PMDD, as proving an effect against such a high placebo effect would require thousands of patients but we are continuing our fully-funded studies for menstrual migraine and Tourette syndrome.

MENSTRUAL MIGRAINE

80% of patients were recruited for our phase IIa menstrual migraine study by the end of Q1 2020. During the quarter we opened a new study site in Lund, southern Sweden. Due to the Covid-19 pandemic, three sites in Finland and one site in Sweden temporarily postponed further recruitment during the quarter, but all centers except the Stockholm center began recruiting again by the middle of May 2020. The study is scheduled to be completed during Spring 2021.

TOURETTE SYNDROME

Plans and funding remain in place for our phase IIa study in Tourette syndrome due to be initiated in Q2 2021. We had a positive, productive consultation with the Danish Medical Agency in the beginning of March to discuss the necessary tox study and proposed clinical protocol. We are also in the process of submitting an application for orphan drug designation with both FDA and EMA that we hope will be approved before the end of 2020.

BEYOND PMDD

Asarina Pharma was reasonably well-funded prior to our PMDD study outcome. We have now reorganized and revised all budgets to ensure that our clinical studies in both menstrual migraine and in Tourette can be completed without any additional funding being required. We were well underway to be phase III-ready in terms of production upscaling, development of a tailor-made autoinjector for the Sepranolone product and so on. Over the coming months we will mothball these activities, stopping them for now, but in a state where they can be quickly resumed when our menstrual migraine study hopefully yields positive results.

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About Asarina Pharma

We are a Swedish biotech company developing Sepranolone for allopregnanolone-related stress, menstrual and neurological disorders. Our product pipeline is built on over 40 years of research into allopregnanolone-related neurological disorders. With our new family of GAMSAs compounds (GABA_A Modulating Steroid Antagonists) we aim to deliver a new generation of efficacious and safe drugs for still widely untreated neuroendocrinological conditions.

The information above was provided by Asarina Pharma AB (publ) through the above contact person, for publication on May 26, 08.00, 2020.