SYNACT PHARMA

Press Release
14 September 2022 07:00:00 CEST

Approval of amended study protocol for the Phase 2a study in iMN

SynAct Pharma AB (publ) ("SynAct") today announced that the protocol amendment of the ongoing SynAct-CS003 study with the Company's candidate drug AP1189 in idiopathic membranous nephropathy (iMN) patients with severe proteinuria and/or Nephrotic Syndrome (NS) has been approved.

SynAct wants to explore the opportunity to treat iMN patients for up to 3 months with AP1189 tablets. Therefore, and as previously communicated, the Company submitted a major amendment to the study protocol in July 2022, which has now been approved by the Danish Medicines Agency and is being assessed in Sweden and Norway.

"AP1189 is enabling resolution of inflammation and we believe that it can be a beneficial treatment option in kidney diseases, such as iMN, where there is a significant medical need for new effective and well tolerated treatments. Together with our investigators, we are ready to continue this study according to the improved protocol and investigate the potential of AP1189" said Thomas Jonassen, CSO SynAct Pharma.

SynAct aims to enroll a minimum of 18 patients to the study and expect to complete and report key results during 2023.

The information was submitted, through the agency of the contact person below, for publication at 07: 00 a.m. CEST on September 14, 2022.

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About SynAct Pharma AB
SynAct Pharma AB conducts research and development in inflammatory diseases. The company has a platform technology based on a new class of drug candidates aimed at acute deterioration in chronic inflammatory diseases with the primary purpose of stimulating natural healing mechanisms. For more information: www.synactpharma.com.

About AP1189
The mechanism of action of SynAct Pharma´s candidate drug, AP1189, is to promote resolution of inflammation through selective activation of melanocortin receptors 1 and 3. These receptors are located on all immune cell types including macrophages and neutrophils. Activation of these receptors results in two direct anti-inflammatory effects: it turns these cells to produce less pro-inflammatory molecules and also to switching them to perform inflammation “clean-up”, known as efferocytosis (J Immun 2015, 194:3381-3388). This effect has shown to be effective in disease models of inflammatory and autoimmune diseases and the clinical potential of the approach is currently tested in clinical programs in patients with rheumatoid arthritis (RA), nephrotic syndrome (NS) and COVID-19. The safety and efficacy of AP1189 is being tested and has not been reviewed by any regulatory authority worldwide.

About SynAct-CS003
SynAct-CS003 is an exploratory, randomized, double-blind, placebo-controlled study to testing the effect of a once daily dose of 100 mg AP1189 tablets vs placebo for 12 weeks as add-on to treatment with ACE-inhibitors/ angiotensin II receptor blocker treatment in iMN patients with severe proteinuria and/or nephrotic syndrome (12 patients will be treated with 100 mg AP1189 and 6 patients will be treated with placebo). The primary endpoints are to assess safety and efficacy measured as change in urinary protein excretion from baseline to end of treatment. Recruitment to SynAct-CS003 occurs at 7 clinical sites in Denmark, Sweden and Norway.

Attachments
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