SynAct Pharma takes advantage of new toxicology results and new tablet formulation to re-design and optimize the study programme with AP1189 in Nephrotic Syndrome

SynAct Pharma today announces that the company intends to redesign the phase 2 development program with the lead asset AP1189 in Nephrotic Syndrome (NS). The aim of this is to take advantage of longer treatment periods now possible following new preclinical documentation published on November 5th this year. In addition, the redesigned study will take advantage of the company´s newly developed tablet, published on October 15 this year.

The major aim of the redesign will be to increase dosing from four weeks to three months and change from dosing with the AP1189 suspension and instead dose with tablets. The benefit of this redesign is that it increases the likelihood to show significant treatment effect on urinary protein excretion, the main efficacy readout in the study, and increase patient compliance as a once daily dosing with a tablet is much more convenient than daily intake of an oral suspension.

SynAct Pharma's phase 2 study in NS is conducted in patients with idiopathic membranous nephropathy (iMN), an autoimmune kidney disease associated with development of NS and is ongoing at sites in Denmark and Sweden. In the current study, an exploratory, randomized, double-blind, multicenter, placebo-controlled study, the AP1189 compound versus placebo is given once-daily as add-on to ACE-inhibitor treatment in patients with NS due to iMN. As for most other clinical studies, recruitment has suffered from the effects associated with the COVID-19 pandemic. Consequently, recruitment to the current study is therefore not completed.

The current study focuses on safety, tolerability, and pharmacokinetics (PK). The latter is of specific importance as the major loss of protein through the kidneys potentially could have marked effects on the body's exposure to AP1189 and thereby the efficacy of a given dose. In addition, efficacy is evaluated though the compound's ability to reduce urinary protein excretion. However, the full effect of the compound's ability to reduce urinary protein excretion is not likely to take place during a 4-week treatment period. The possibility to dose for three months is therefore a major advantage for the project moving forward.

"The redesign will take benefit of the already generated experiences in the patient population and the collected data and samples will be an integrated part of the final study report. However, in addition to the benefits of three-month dosing and the new tablets, we intend to reduce the complexity of the study design, especially related to PK sampling and thereby increase acceptability for the patients and with this ease study recruitment. The possibility to broaden recruitment to other indications associated with NS is currently examined as it would give the possibility to increase recruitment rates significantly. Finally, the redesign has been discussed with potential future pharma partners and is likely to improve the commercial attractiveness even further. We plan to present the new study design with updated timelines in continuation of the release of key results of our BEGIN study in RA" says Thomas Jonassen, CEO, SynAct Pharma.

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For further information about SynAct Pharma AB, please contact:

Jeppe Øvlesen
CEO, SynAct Pharma AB
Phone: +45 28 44 75 67
Mail: joo@synactpharma.com

Thomas Jonassen
CSO, SynAct Pharma AB
Phone: +45 40 15 66 69
Mail: tj@synactpharma.com

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 lead compound 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 phase 2a studies in patients with active 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.