Press release

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SynAct Pharma updates development plans

SynAct Pharma AB ("SynAct") today announces that the company expects to release interim data from the ongoing phase IIa study of AP1189 in rheumatoid arthritis (RA) patients during Q2 2020 instead of Q1, as previously announced. The delay of the first part of the phase IIa study will not impact the reporting of the topline results from the full phase IIa study, which will include both part 1 and part 2 of the study. This means, as previously informed, that the topline results from the full phase IIa study will be released in Q1 2021.

The clinical development activities for studying AP1189 in nephrotic syndrome (NA) are moving ahead according to plans and the clinical trial application will be filed in Q1 2020 with topline results also planned for Q1 2021.

The delay in the RA clinical study of one quarter does not impact the runway, meaning that the proceeds received from the recent issue, as well as the funds planned to be received from TO2 warrants, will cover the company's cost until the planned reporting of the RA and NS study.

The phase IIa clinical trial entitled "A double-blind, multi-center, two-part, randomized, placebo-controlled study of the safety, tolerability, and efficacy of 4 weeks of treatment with AP1189 in early rheumatoid arthritis (RA) patients with active joint disease", is ongoing with active recruitment of patients in Denmark and Sweden and from this month also in Norway. Previous methotrexate naïve patients with active RA are randomized in the study, with a daily oral intake of AP1189 or placebo treatment, as an add-on to methotrexate therapy for four weeks. The interim data from part one of the study will form the basis for our decision on the dose to be used for the second part of the study and will be ready in Q2 2020. As previously informed, the reporting of topline results from the full phase IIa study (both part 1 and part 2) is planned for Q1 2021.

The delay of the RA study is caused by an enrolment, which due to unexpected low referral of eligible patients to the clinical sites, has been lower than anticipated. The enrolment rate is now on track.

To meet the overall timeline for the study, SynAct has expanded the study to other European sites through the establishment of a collaboration agreement with Nordic Bioscience Clinical Development A/S, a company with substantial expertise in chronic joints diseases, including RA, gained from their clinical development engagements. Under SynActs agreement with Nordic Bioscience, Nordic Bioscience will be responsible for enrolling patients for the phase IIa study from sites that in previous studies has secured fast on-time recruitment.

The CTA for the phase IIa study in NS will be filed in Denmark and Belgium in Q1 2020 as planned and communicated with the topline report planned for Q1 2021.

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This information is such information that SynAct Pharma AB is obliged to publish in accordance with the EU Market Abuse Regulation. The information was submitted, through the agency of the above contact person, for publication on February 7, 2020.

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.