SYNACT PHARMA

Press Release
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SynAct Pharma announces additional data from the EXPAND P2b clinical trial supporting continued development of the compound in rheumatoid arthritis

SynAct previously released a post-hoc analysis of the EXPAND trial of once-daily oral resomelagon in treatment naïve rheumatoid arthritis patients who had an elevated baseline level of C-reactive protein (CRP> 3mg/L), marker of systemic inflammation. To further this assessment, a subset analysis of the elevated baseline CRP patients who were enrolled within 6 months of their diagnosis of rheumatoid arthritis (RA) was conducted. In this subpopulation of patients, 100mg of daily resomelagon demonstrated a consistent and statistically significant response to therapy over placebo across assessed outcome measures.

At 12 weeks in EXPAND patients with elevated baseline CRP, the 100mg resomelagon group had an ACR20 attainment of 71% as compared to 54% of placebo patients. At 12 weeks in the subpopulation of patients with elevated CRP who were enrolled and had treatment initiated within 6mo of their RA diagnosis, 23 out of 28 (82%) of patients treated with 100mg resomelagon attained an ACR20 compared to 14 out of 27 (52%) of placebo patients ($P<0.05$). A significant difference favoring resomelagon was also seen across the secondary outcome measures including the reduction in CDAI (resomelagon 24.6 vs placebo 14.7 points, $p<0.01$), reduction in DAS28-CRP (resomelagon 1.9 vs placebo 1.2 points, $p<0.01$), and reduction in HAQ disability index (0.69 vs placebo 0.31 points, $p<0.05$). Safety in the elevated CRP population with treatment within 6 months of was comparable to what has been previously reported for the full EXPAND study population.

Thomas Jonassen, CSO SynAct Pharma said: “These data strongly further support continued development of resomelagon in RA patients particularly in those patients who are treated in line with US and European guidelines that recommend early treatment with first-line therapy particularly in patients presenting with severe disease activity like those recruited into the EXPAND study. The guidelines further emphasize that second line treatment should be implemented as early as three months into MTX treatment in case of no primary treatment effect, and no longer than 6 months in the absence of adequate disease control”.

“This subpopulation analysis of the EXPAND elevated baseline CRP patients reinforces the efficacy seen in the elevated CRP population and indicates the high level of responsiveness seen in patients who are early in their course of disease. We know from published data that 50% or more of the patients treated initially with methotrexate will initiate second-line therapy in that first 6-month period. Typically, these patients are treated with an anti-TNF agent or other biologic agent. We feel that a once-daily oral therapy like resomelagon would be a very attractive alternative to stepping up to a biologic therapy which are associated with rare but significant safety concerns and require self-injection or infusion-based administration,” stated stated Torbjörn Bjerke, CEO of SynAct Pharma. “This is a population of high unmet need and is a population of high interest to our prospective partners”.

SynAct will hold a conference call for Q4 report for 2023 on February 23 at 15.00 CET where this release will be discussed and where questions may be posed.

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About SynAct Pharma AB
SynAct Pharma AB (Nasdaq Stockholm: SYNACT) is a clinical stage biotechnology company focused on the resolution of inflammation through the selective activation of the melanocortin system. The company has a broad portfolio of oral and injectable selective melanocortin agonists aimed at inducing anti-inflammatory and inflammation resolution activity to help patients achieve immune balance and overcome their inflammation. For more information: www.synactpharma.com.

Attachments
SynAct Pharma announces additional data from the EXPAND P2b clinical trial supporting continued development of the compound in rheumatoid arthritis