JJP Biologics announces positive decision to execute a First-in-Human clinical trial of anti-inflammatory mAb JJP-1212 (anti-CD89)

JJP Biologics has received a positive conclusion on the Clinical Trial Application assessment for a Phase I Study of a potential first-in-class anti-CD89 antagonist, JJP-1212 monoclonal antibody for the treatment of various IgA-mediated autoimmune- and fibrotic diseases.

Warszawa Wednesday, May 29, 2024

On May 27, 2024 the European Medicines Agency, issued a positive decision on our first Clinical Trial Application to conduct a phase I clinical study in healthy participants (EudraCT: 2023-508661-33-00) with a potential first-in-class anti-CD89 antagonist, JJP-1212 monoclonal antibody for the treatment of various IgA-mediated autoimmune- and fibrotic diseases.

Up to date, JJP Biologics is the first Polish company to receive approval to perform the First-in-Human clinical trial with a novel therapeutic monoclonal antibody.

This decision is an important milestone for patients suffering from IgA-mediated autoimmune or fibrotic diseases and validates the preclinical package of JJP-1212.

The phase I trial will be carried out in Poland. The study endpoints are designed for a comprehensive evaluation of the treatment's safety profile. The drug will be administered via intravenous infusion in single and multiple ascending dose cohorts. Population size was determined as 48 healthy adult volunteers.

The study results will provide data on the safety and tolerability of JJP-1212, and full PK/PD profiles that subsequently enable the determination of optimal treatment regimens in future studies with patient populations. JJP Biologics intends to use phase I read-outs as supporting data for a set of phase II trials, in a range of therapeutic areas, and regions (including EU and the US).

The expected study results will not only validate the safety but also contribute to deciding on extension of JJP-1212’s development scope in various therapeutic areas, beyond dermatology.

According to Paweł Szczepański, COO and Management Board Member at JJP Biologics - “This is a historically unprecedented approval of a first-in-human clinical trial for a novel large molecule therapy from Poland. It forms a landmark that will further strengthen the position of the Polish biotech sector on the global map blazing the trail for many innovative therapies to come from this part of Europe. Including the next ones from the development platform of JJP Biologics”.

JJP-1212 is a first-in-class IgG4-κ anti-CD89 antagonist that is being developed to treat autoimmune and fibrotic diseases in which IgA autoantibodies are a key element of the disease pathophysiology. Alongside Linear IgA Bullous Dermatosis (LABD), JJP-1212 is being developed for a wide range of autoimmune- and

fibrotic diseases where IgA is known to have significant pathogenic involvement (e.g. rheumatoid arthritis, axial spondyloarthritis, systemic lupus erythematosus, neutrophilic asthma, chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis, cystic fibrosis, hidradenitis suppurativa, nonalcoholic steatohepatitis, IgA nephropathy, IgA vasculitis). JJP Biologics is exploring the development of companion diagnostics in various indications using serum IgA autoantibodies as biomarkers for personalized treatment with JJP-1212.

JJP BIOLOGICS

JJP Biologics is a clinical-stage biotechnology company that specializes in the development of therapeutic monoclonal antibodies accompanied by companion diagnostics for personalized treatment. JJP Biologics pursues the development of its product candidates as well as projects executed in cooperation with scientific partners. The company's programs target general immune pathways that have applications in autoimmune diseases and cancer. JJP Biologics' pipeline includes the most advanced JJP-1212, a potential first-in-class anti-CD89 antagonist for the treatment of autoimmune- and fibrotic diseases, and JJP-1008, a potential first-in-class anti-CD270 checkpoint inhibitor, for solid tumors. The JJP-1212 Project is co-financed by the state budget by the Polish Medical Research Agency (No: 2022/ABM/05/00011).

JJP Biologics is a privately funded biotech, partially financed from programs run by the Polish Medical Research Agency. In 2022, JJP Biologics became the first Polish company whose biological drug candidate (JJP-1212) received an Orphan Drug Designation from the European Commission, following the recommendation of the European Medicines Agency.