JJJP Biologics announces initiation of the Multiple Ascending Dose (MAD) part of its Phase I Clinical Trial for JJP-1212

JJP Biologics announces the start of the MAD part in the ongoing Phase I Clinical Trial of a new investigational medicinal product JJP-1212, a first-in-class CD89 antagonist in healthy volunteers, to complete the safety and PK/PD assessment.

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Warsaw, Poland – JJP Biologics, a Polish innovative biopharmaceutical company focused on developing novel therapies for autoimmune and oncological diseases, announces the initiation of the Multiple Ascending Dose (MAD) part of its Phase I clinical trial for JJP-1212. This milestone marks a step forward in the development of JJP-1212 for the treatment of autoimmune and fibrotic diseases.

The Phase I trial (EU trial number: 2023-508661-33-00) is a randomized, double-blinded, placebo-controlled study designed to evaluate the safety, tolerability, and pharmacometrics, of a new investigational medicinal product JJP-1212 in healthy adult volunteers. The study is divided into a single ascending dose (SAD) part and multiple ascending dose (MAD) part. The MAD part of the trial will assess the safety parameters of three subsequent administrations of JJP-1212 in two dosing cohorts. This part of the study will deliver valuable clinical information on safety profile, pharmacokinetic and pharmacodynamic data of JJP-1212.

“The MAD part of our Phase I is critical to determine the safety of JJP-1212 over prolonged periods and repetitive dosing that might be needed to treat certain chronic autoimmune and/or fibrotic indications. Therefore, we are delighted with the decision of the dose escalation committee to continue to our first MAD cohort. ” said Louis Boon, Chief Scientific Officer and Board Member at JJP Biologics.

About JJP-1212

JJP-1212 is a first-in-class anti-CD89 antagonist IgG4-κ monoclonal antibody that inhibits immunoglobulin A (IgA) mediated activation of myeloid cells. The presence of IgA-containing immune complexes or IgA tissue deposits has been associated with the progression and severity of various autoimmune and fibrotic diseases. JJP Biologics is developing a companion diagnostic for various indications using serum IgA autoantibodies as biomarkers to stratify patients for personalized treatment with JJP-1212.

The European Medicines Agency granted JJP-1212 the orphan designation (EU/3/22/2702) for the treatment of linear IgA dermatosis patients (LAD). With the recent phase I clinical trial authorization by the Office for Registration of Medicinal Products in Poland, JJP-1212 became the first new biologic treatment in the history of the Polish biotechnology sector to enter the clinical phase.

The JJP-1212 project is co-financed from the state budget by the Polish Medical Research Agency (No: 2022/ABM/05/00011).

JJP BIOLOGICS

JJP Biologics is a privately funded, clinical stage biotechnology company that specializes in the development of therapeutic monoclonal antibodies accompanied by companion diagnostics for personalized treatments. JJP Biologics pursues the development of its own product candidates as well as projects executed in cooperation with scientific partners. By targeting specific immune pathways, the company's products have broad applications in autoimmune diseases and cancer. JJP Biologics' current product pipeline includes the most advanced JJP-1212, a first-in-class anti-CD89 antagonizing monoclonal antibody for the treatment of various autoimmune and fibrotic diseases, and JJP-1008, a first-in-class CD270 immune checkpoint inhibiting monoclonal antibody, for the treatment of various oncological indications.

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