



Press Release

Abivax Treats First Patient in Phase 2a Rheumatoid Arthritis Clinical Trial of ABX464

Rheumatoid arthritis is a severe, debilitating disease with 4.2 million diagnosed patients in G7 (US, G5 Europe & Japan) countries and pharmaceutical sales of \$24.4 billion in 2018

60-patient trial fully authorized in four European countries

ABX464 Phase 2b Ulcerative Colitis trial progressing well

ABX464 Phase 2a Crohn's disease trial to start Q4 2019 or Q1 2020

PARIS, August 1, 2019, 6:00 p.m. CEST – Abivax (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biotechnology company harnessing the immune system to develop novel treatments for inflammatory diseases, viral diseases and cancer, announced today that the first patient was dosed in study ABX464-301, a phase 2a clinical trial of ABX464 to treat patients with moderate to severe active rheumatoid arthritis (RA). The trial has been fully approved in four countries (France, Poland, Czech Republic, and Hungary). ABX464 is an oral once-daily drug candidate with a novel mechanism of action that has already demonstrated positive results in ulcerative colitis (UC), another severe chronic inflammatory disease with closely related biological etiology.

“We are pleased to initiate the first clinical trial of ABX464 in patients with moderate to severe active rheumatoid arthritis, the largest market opportunity in inflammatory disease. The robust, sustained Phase 2a clinical ulcerative colitis efficacy, demonstrating ABX464’s rapid, potent anti-inflammatory effects, together with ABX464’s broad efficacy in preclinical inflammatory disease models, suggest that ABX464 may have important potential as a novel, highly differentiated anti-inflammatory therapeutic agent,” said **Professor Hartmut J. Ehrlich, MD, Chief Executive Officer of Abivax**. *“ABX464’s novel mechanism of action, published in [Nature Scientific Reports](#) in January 2019, illustrates how this orally available molecule is differentiated and offers a potentially complementary mechanism of action compared to marketed anti-inflammatory agents.”*

Professor Ehrlich continued: *“Thanks to the [recent EUR12 million investment](#) by Sofinnova Partners, we are moving, as planned, to accelerate the development of this first-in-class therapeutic candidate to treat rheumatoid arthritis. Also, the phase 2b trial of ABX464 to treat ulcerative colitis is progressing well, with the “first patient dosed” expected for the next two weeks. Furthermore, we look forward to initiating, around the end of this or early next year, a phase 2a trial of ABX464 to treat Crohn’s disease.”*

The Phase 2a Clinical Trial with ABX464 in Rheumatoid Arthritis

ABX464-301 is a phase 2a study designed to evaluate the safety, tolerability and preliminary efficacy of two oral dose-levels of ABX464 administered daily, in combination with methotrexate (MTX), in patients with moderate to severe active RA who had an inadequate response to MTX and/or to one or more anti-tumor necrosis factor alpha (TNF α) biological therapeutics. It is a randomized, double-blind, placebo-controlled, multicenter study in sixty patients with moderate to severe active RA, who will receive 50 mg ABX464, 100

mg ABX464, or placebo during the twelve-week treatment phase. The primary endpoint of the study will be safety and tolerability. Secondary endpoints will include measures of efficacy, such as: change from baseline in the individual components of the American College of Rheumatology (ACR) score; proportion of patients achieving ACR20 response; and, change from baseline in Disease Activity Scores (DAS) in 28 joints. Top-line data from this clinical trial are expected in about one year, during the summer of 2020. For further details, please click [here](#).

Dr. Jean-Marc Steens, Chief Medical Officer of Abivax commented: *“Rheumatoid arthritis is an irreversible, debilitating, and systemic autoimmune disease that often requires aggressive treatment to control. This disease represents a major burden for the millions of affected patients, their families and for healthcare systems worldwide. The standard of treatment has substantially evolved during the past two decades, now including conventional disease-modifying antirheumatic drugs (DMARDs) used as first line, like methotrexate, leflunomide, hydroxychloroquine, sulfasalazine but also biologic DMARDs (anti-TNF) as well as targeted DMARDs (JAK-inhibitors). However, too many patients do not respond or loose responsiveness to these drugs, and new molecules with a different mechanism of action, like ABX464, are needed.*

About ABX464

ABX464 was shown to exert its anti-inflammatory effects through a novel mechanism of action; it binds to the cap binding complex (CBC), which essentially sits at the 5' end of every RNA molecule in the cell. By binding to the CBC, ABX464 reinforces the biological functions of this complex in cellular RNA biogenesis. Specifically, ABX464 enhances the selective splicing of a single long non-coding RNA to generate the anti-inflammatory microRNA miR-124, which downregulates pro-inflammatory cytokines and chemokines like TNF- α , Il-6 and MCP-1, thereby putting a brake on inflammation and suggesting broad potential as a novel anti-inflammatory therapeutic agent. In phase 2a testing ABX464 treatment, a seven- to ten-fold increase of miR124 was observed in peripheral blood mononuclear cells (PBMCs) and in colorectal biopsies of UC patients. ABX464 does not impact the splicing of cellular genes.

ABX464 in Inflammatory Diseases⁽¹⁾

Despite the success of marketed therapies, the inflammatory disease space represents an area of high unmet medical need and a corresponding substantial market opportunity. It is estimated that about 4,2 million patients are diagnosed with RA in the G7 (US, G5 Europe & Japan) countries and the pharmaceutical sales in this indication were \$24.4 billion in 2018. At the same time, over 2.7 million people are diagnosed with ulcerative colitis globally, representing a potential market opportunity of up to \$5.6 billion annually (G7), based on 2018 pharmaceutical sales in this sector. For IBD (UC and Crohn's disease), pharmaceutical sales during this same period are estimated to have reached nearly \$16 billion. The market potential for the full range of inflammatory conditions (including neuro-inflammatory diseases) is currently estimated to be in excess of \$70 billion, a market and patient population that the Company believes could benefit from ABX464.

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is an autoimmune disease in which the body's immune system mistakenly attacks the joints, resulting in inflammation that causes tissue damage and swelling. If untreated, inflammation can also damage cartilage and the bones themselves, which lead to bone friction, chronic pain, as well as irreversible deformity and loss of mobility. RA most commonly affects the joints of the hands, feet, wrists, elbows, knees and ankles, however, can also affect body systems such as the cardiovascular or respiratory systems, making it a systemic disease. Women are three times more likely to be affected as men.

About ABIVAX (www.abivax.com)

ABIVAX is mobilizing the body's natural immune machinery to treat patients with viral infections, autoimmune diseases and cancer. A clinical-stage company, ABIVAX leverages its antiviral and immune enhancing platforms to optimize candidates to treat ulcerative colitis and other inflammatory diseases, viral diseases and liver cancer. ABIVAX is listed on Euronext compartment B (ISIN: FR0012333284 – Mnémo: ABVX). More information on the company is available at www.abivax.com/en. Follow us on Twitter @ABIVAX_ and [LinkedIn](#).

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