Press Release

Abivax Receives First Clinical Trial Authorization for ABX464 Phase 2a Study in Patients with Rheumatoid Arthritis

French agency (ANSM) first to approve clinical trial trial with ABX464 in moderate to severe rheumatoid arthritis

Trial to be conducted in 60 patients in five countries, with "first patient in" scheduled for early Q3 2019

Rheumatoid arthritis is a severe, debilitating disease with 4,2 million diagnosed patients in G7 (US, G5 Europe & Japan) countries and pharmaceutical sales (G7) of $24.4 billion in 2018.

PARIS, June 4, 2019, 8:00 a.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 France is the first country to have fully authorized its phase 2a clinical trial application of ABX464 for treatment of patients with moderate to severe active rheumatoid arthritis (RA). The first patient is scheduled to be enrolled in the study in early Q3 2019. In total, the clinical trial will be conducted in five European countries: France, Belgium, Poland, Czech Republic, and Hungary. ABX464, a once daily, oral drug candidate with a novel mechanism of action, already demonstrated positive results in another severe chronic inflammatory disease, ulcerative colitis.

"Consistent with Abivax' strategy to explore the full potential of its lead compound ABX464 and pursue additional inflammatory indications, following our exciting ulcerative colitis clinical data, we are pleased to have received full regulatory and ethical clearance of our first clinical trial of ABX464 in patients with moderate to severe active rheumatoid arthritis in the first country", said **Professor Hartmut J. Ehrlich, MD, Chief Executive Officer of Abivax**. *"The choice of rheumatoid arthritis as a second inflammatory indication for ABX464 studies was based on three factors: the findings from the January 2019 publication of ABX464's novel mechanism of action in Nature Scientific Reports, the promising pre-clinical data from collagen-induced arthritis animal models with ABX464, and the excellent results from our completed Phase 2a induction study as well as the ongoing maintenance trial of ABX464 in ulcerative colitis patients."*

Professor Ehrlich continued*: "Not only did our preclinical reseach indicate ABX464's broad applicability across a spectrum of debilitating inflammatory diseases, but our phase 2a results in ulcerative colitis substantiate its long-term safety, as well as the rapid onset and lasting duration of its robust clinical anti-inflammatory response. Based on these considerations, we have decided to accelerate the development of this highly differentiated, oral, first-in-class therapeutic candidate in rheumatoid arthritis. Based on the data we have in hand, we are confident that we can build strong shareholder value with this new indication."*

The Phase 2a Clinical Trial with ABX464 in Rheumatoid Arthritis

This phase 2a study is 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 Rheumatoid Arthritis (RA) who had an inadequate response to MTX and/or to one or more anti-tumor necrosis factor alpha (TNFα) biologicals. This is a randomized, double-blind, placebo-controlled, multicenter study in sixty patients with moderate to severe active RA , who will be assigned to receive 50mg ABX464, 100mg ABX464 or placebo during the twelve-week treatment phase. The primary endpoint of the

study will be safety and tolerability. Secondary endpoints will be indicators of efficacy including the change from baseline in the individual components of the American College of Rheumatology (ACR), the proportion of patients achieving ACR20 response and change from baseline in Disease Activity Scores (DAS) in 28 joints. 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 and for the healthcare systems worldwide. The standard of care has substantially evolved during the past two decades, now including disease-modifying antirheumatic drugs (DMARDs) such as methotrexate, leflunomide, hydroxychloroquine and sulfasalazine. These drugs, however, can cause liver damage, bone marrow suppression and severe lung infections. In addition, the introduction of biological agents is associated with an increased risk of severe and potentially life-threatening infections. The safety profile of these drugs illustrates the substantial unmet need in therapeutic options that could potentially be addressed by a new oral treatment with a novel mechanism, such as ABX464."*

About ABX464

ABX464 was shown to target the cap binding complex (CBC), which is a novel mechanism of action for anti-inflammatory drugs. By binding to the CBC, ABX464 reinforces the biological functions of this complex in cellular RNA biogenesis including splicing. ABX464 enhances the selective splicing of a single long non-coding RNA to generate the anti-inflammatory microRNA miR-124, which acts by downregulating pro-inflammatory cytokines and chemokines like TNF-α, Il-6 and MCP-1, thereby putting a brake on inflammation. A seven- to ten-fold increase of miR124 was observed in peripheral blood mononuclear cells (PBMCs) of healthy volunteers upon incubation with ABX464, and in colorectal biopsies of UC patients treated with the drug candidate.

ABX464 in Inflammatory Diseases[1]

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[2]

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. Rheumatoid arthritis 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.

[1] Source : GlobalData
[2] Source: Arthritis Foundation, https://www.arthritis.org/

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_

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