Abivax phase 2a study results of obefazimod (ABX464) in rheumatoid arthritis published in the journal “Annals of the Rheumatic Diseases” and selected for presentation at EULAR 2022

June 1, 2022

Phase 2a safety and efficacy study results of obefazimod (ABX464) in patients with rheumatoid arthritis (RA) published in the renowned and peer-reviewed journal “Annals of the Rheumatic Diseases (ARD)” and accepted for presentation at the Annual European Congress of Rheumatology, EULAR 2022

Presentation at EULAR is scheduled for June 1, 2022, at 8:40 p.m. CEST (2:40 p.m. EST) and will be given by principal investigator Claire Daien, M.D., Ph.D. (registered participants only)

“Obefazimod” registered as an international nonproprietary name (INN) for ABX464 at WHO and USAN

PARIS, France, June 1, 2022 – 08:00 a.m. (CEST) – Abivax SA (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biotechnology company developing novel therapies that modulate the immune system to treat chronic inflammatory diseases, viral infections, and cancer, announces today that a scientific article on its phase 2a clinical study results for the treatment of moderate to severe active rheumatoid arthritis (RA) with obefazimod (ABX464) has been published in the renowned peer-reviewed journal “Annals of the Rheumatic Diseases (ARD)”[1]. Further, the abstract on these phase 2a data has been selected for a poster presentation at the Annual European Congress of Rheumatology, EULAR 2022. The presentation will be given by principal investigator Claire Daien, M.D., Ph.D., on Wednesday, June 1, 2022 at 8:40 p.m. CEST (2:40 p.m. EST – accessible for registered EULAR participants only).

Prof. Claire Daien, M.D., Ph.D., rheumatologist at the University Hospital at Montpellier and principal investigator of the study, said: *“I am very excited that our phase 2a clinical data with ABX464, now obefazimod, in patients suffering from rheumatoid arthritis have been published in the prestigious peer-reviewed journal ARD and have further been selected for a poster presentation at EULAR 2022. I am looking forward to presenting obefazimod and its promising results to the international expert community, also taking into account the recently published very encouraging phase 2a one-year maintenance results in RA. There is still a high unmet medical need for safe and durably efficient therapies for rheumatoid arthritis patients. Therefore, alternative treatment options based on a novel mechanism of action, such as obefazimod, are needed.”*

Prof. Paul Emery, M.D., FMedSci, Versus Arthritis Professor of Rheumatology, Director of the Leeds Musculoskeletal Biomedical Research Centre, Leeds Teaching Hospitals Trust, Leeds Institute of Rheumatic and Musculoskeletal Medicine, UK, commented: *“Beyond the promising data of the phase 2a induction study presented at EULAR, the high levels of maintained response rates of the phase 2a maintenance trial with obefazimod in rheumatoid arthritis patients, especially when it comes to ACR50 and ACR70 responses, look also very encouraging. The molecule also demonstrated a good safety profile, and no serious infections were observed. Along with its very different mode of action and clinical profile, obefazimod has the potential to play an important role in the future management of rheumatoid arthritis patients.”*

Prof. Hartmut J. Ehrlich, M.D., CEO of Abivax, added: *“We are very pleased that the results of the phase 2a study in RA clearly confirm the excellent anti-inflammatory effects and favorable safety of obefazimod that have already been demonstrated in phase 2a and 2b trials in ulcerative colitis. The publication of our RA phase 2a induction data in the journal ARD and the selection for a presentation at EULAR are very important for Abivax, as they scientifically validate the capacity of our drug candidate to address RA, in addition to ulcerative colitis and Crohn’s disease, and therefore a broad range of chronic inflammatory diseases. Importantly, obefazimod did not only show a potent and rapid onset of action during the induction studies but, in both our RA and UC maintenance trials, demonstrated a durable efficacy over time. Millions of patients suffering from these chronic and very debilitating diseases are in need of new, safe drugs with long lasting efficacy. The Abivax team is therefore committed to making obefazimod available to these patients as quickly as possible.”*

The clinical phase 2a induction study was designed to evaluate the safety, tolerability, and preliminary efficacy of two oral dose levels of obefazimod administered once daily, in combination with methotrexate (MTX). 60 patients who had an inadequate response to MTX and/or to one or more anti-tumor necrosis factor alpha (TNFα) biological therapeutics participated in this randomized, double-blind, placebo-controlled trial. Patients received obefazimod (50mg or 100mg) or placebo during the 12-week induction treatment phase. The study was conducted in 21 study centers across four European countries (France, Belgium, Poland and Hungary). The treatment groups were well balanced in terms of disease severity as well as patient demographics.

In June 2021, Abivax communicated the results of the induction phase of its phase 2a clinical study. The primary endpoint of this study, safety and tolerability, was met with 50mg obefazimod once daily, demonstrating good safety and tolerability profile in the overall patient population during the 12-week induction phase.

67% (40/60) of the patients who completed the induction study enrolled in the open-label extension maintenance study to receive 50mg obefazimod orally once a day for an additional year.

In March this year, Abivax reported exciting results from the phase 2a maintenance trial in RA.

58% of the patients (23/40) suffering from moderate to severe active RA completed 52 weeks of chronic treatment with obefazimod. Efficacy of 50mg once daily obefazimod was assessed by the DAS28-CRP remission (DAS28-CRP < 2.6[2]) and the ACR20/50/70[3] rates.

57% of the patients (13/23) were in remission at week 52, assessed by the DAS28-CRP (< 2.6), corresponding to 33% (13/40) using the full analysis set (FAS).

All 23 patients (100%) who completed 52 weeks of treatment achieved at least an ACR20 response, which translates into 58% (23/40) in the FAS. It is remarkable, that according to the observed cases population, 83% (19/23) and 52% (12/23) achieved even an ACR50 and ACR70 response respectively, corresponding to 48% (19/40) and 30% (12/40) according to the FAS.

20/23 patients were eligible to continue their treatment after week 52 and are at present in their second year of continued daily oral treatment with 50mg obefazimod.

Obefazimod was safe and the nature of the adverse events is consistent with what has been observed in more than 1,000 subjects who have so far

been treated in other clinical trials with obefazimod across different indications.

Abivax currently focuses on the development of obefazimod for the treatment of ulcerative colitis and recently reported excellent phase 2b one-year maintenance data in this indication. A phase 3 clinical program in ulcerative colitis is under finalization and the first patient is planned to be included in Q3 2022.

The outcome of the clinical studies conducted in UC, along with the promising results of the obefazimod phase 2a induction as well as the maintenance study after one year of continued treatment in RA patients, underpin the potential of obefazimod to treat a broad range of chronic inflammatory diseases.

"Obefazimod" registered as INN for ABX464

Abivax further announces today that "obefazimod" has been confirmed as international nonproprietary name (INN) for drug-candidate ABX464. Obefazimod has officially been registered and published at the WHO as well as the USAN (United States Adopted Names).

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About Abivax (www.abivax.com)

Abivax, a clinical stage biotechnology company, is developing novel therapies that modulate the body's natural immune machinery to treat patients with chronic inflammatory diseases, viral infections, and cancer. Abivax is listed on Euronext compartment B (ISIN: FR0012333284 – Mnémo: ABVX). Based in Paris and Montpellier, Abivax has two drug candidates in clinical development, obefazimod (ABX464) to treat severe inflammatory diseases, and ABX196 to treat hepatocellular carcinoma. More information on the company is available at www.abivax.com. Follow us on Twitter @ABIVAX_.

Contacts

Abivax
Communications
Regina Jehle
regina.jehle@abivax.com
+33 6 24 50 69 63

Investors
LifeSci Advisors
Ligia Vela-Reid
lvela-reid@lifesciadvisors.com
+44 7413 825310

Press Relations & Investors Europe
MC Services AG
Anne Hennecke
anne.hennecke@mc-services.eu
+49 211 529 252 22

Public Relations France
Actifin
Ghislaine Gasparetto
ggasparetto@actifin.fr
+33 6 21 10 49 24

Public Relations France
Primatice
Thomas Roborel de Climens
thomasdeclimens@primatice.com
+33 6 78 12 97 95

Public Relations USA
Rooney Partners LLC
Jeanene Timberlake
jtimberlake@rooneypartners.com
+1 646 770 8858

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[1] Annals of the Rheumatic Diseases: "Safety and efficacy of the miR-124 upregulator ABX464 (obefazimod, 50 and 100 mg per day) in patients with active rheumatoid arthritis and inadequate response to methotrexate and/or anti-TNFα therapy: a placebo-controlled phase II study", ARD, 2022.

[2] DAS28-CRP-Disease Activity Score for 28 joints - C reactive Protein

[3] The American College of Rheumatology ACR score measures the efficacy of treatments for rheumatoid arthritis patients. The ACR20/50/70 measures a 20/50/70% improvement in the tenderness and swelling in designated joints and a 20/50/70% improvement in at least 3 of the 5 following measures: investigator's and patient's reported global assessment of disease scales, patient's reported pain scale, CRP level, healthy assessment questionnaire.