

## **Kymab Announces Positive Phase 2a Results for KY1005 in Moderate to Severe Atopic Dermatitis**

- KY1005 met both primary end points demonstrating:
  - A clinically meaningful improvement in disease activity compared to placebo, as measured by percentage of change from baseline in the Eczema Area and Severity Index (EASI) in patients inadequately controlled by topical corticosteroids from baseline to week 16
  - Safety with an acceptable adverse event and tolerability profile
- KY1005 is a fully human monoclonal antibody that has a novel mechanism of action, it binds to OX40-Ligand (OX40L) and has the potential to treat a wide variety of immune-mediated diseases and inflammatory disorders

**Cambridge, UK, 11 August 2020:** Kymab, a clinical-stage biopharmaceutical company developing fully human monoclonal antibodies with a focus on immune-mediated diseases and immunology therapeutics, announced today that the primary endpoints in its Phase 2a (NCT03754309), randomized, double-blinded, placebo-controlled study have been met.

The proof of concept study, conducted across 20 European sites, evaluated the efficacy, safety and tolerability of KY1005 in 88 adults with moderate to severe atopic dermatitis whose disease could not be adequately controlled with topical corticosteroids. Patients were randomised into one of two dose groups of KY1005 or placebo and treated for 12 weeks. The primary endpoint was assessed 4 weeks later. Data from the study will be published in the fourth quarter of this year.

“The data from this atopic dermatitis study is extremely promising,” said Simon Sturge, Chief Executive Officer. “Moderate to severe atopic dermatitis is a severe, debilitating disease. We are very encouraged by what we have seen and look forward to the long-term results from an assessment out to 6 months after the last dose to evaluate the persistence of response. Not only do these data validate KY1005 as a potential novel therapeutic for the treatment of atopic dermatitis, they also provide a platform to explore its effect in multiple other immune-mediated diseases.”

“There is significant potential for this drug based on these early data, and the scientific rationale is compelling,” said Professor Thomas Bieber MD, PhD, MDRA, Professor of Dermatology and Allergy, Department of Dermatology and Allergy at the University Hospital in Bonn, Germany, who led the trial’s independent safety review committee. “It targets something that many people have completely underestimated in the pathogenesis of AD, antigen presenting cells. Targeting antigen presentation really does appear to be a novel and valid strategy for the treatment of atopic dermatitis.”

“The strength of these early data demonstrates that KY1005 has the potential to be an exciting and attractive therapeutic option for chronic inflammatory diseases such as atopic dermatitis and has the potential to be disease-modifying,” said Dr. Sonia Quaratino, MD PhD, Chief Medical Officer. “Given KY1005’s novel mechanism of action targeting OX40L, which sustains T cell activation and the inflammatory (Th2/1/17/22) pathways implicated in the pathogenesis of different diseases, it could have a broad therapeutic effect and the potential to treat other inflammatory and immune-mediated diseases.”

###ENDS###

## NOTES TO EDITORS

### **About KY1005 and its target, OX40L – a Key Regulator of T cell Activation**

KY1005, a fully human monoclonal antibody, is a first-in-class novel biological therapeutic that may address an underlying T cell immune dysregulation in patients with immune-mediated conditions. It binds to OX40L and prevents it from engaging with OX40 expressed on activated T cells, therefore blocking a prolonged response in T-cells, which can lead to diseases of the immune system and damaging effects on patients. By blocking OX40L-OX40 interaction, KY1005 may act to bring the immune system back into balance by suppressing pro-inflammatory T effector cells and maintaining anti-inflammatory T regulatory cells. This could lead to a profound clinical impact in autoimmune and immune-mediated conditions. Many of the current treatments for these diseases tend to broadly suppress the immune system thus having the potential for significant side effects in some patients. One of the potential advantages of KY1005 is that it could be a more targeted treatment.

OX40L is expressed on activated antigen presenting cells such as B cells, dendritic cells and macrophages, whereas its receptor OX40 is expressed on activated T cells. Both OX40L and OX40 are present at low levels in resting immune cells. The binding of OX40L to OX40 triggers immunostimulatory activities including the secretion of IL-4 and IL-13 which drives the proliferation and longevity of pro-inflammatory effector T cells, an increase in the production of pro-inflammatory cytokines, suppression of anti-inflammatory regulatory T cell activity, preservation of cellular memory and facilitation of cell migration. In line with these important modulatory functions, OX40L and OX40 have been found to play a pivotal role in the development of immune mediated diseases, making them attractive candidates for intervention in the clinic.

### **About the KY1005 Phase 2a Study**

The Phase 2a clinical trial (<https://clinicaltrials.gov/ct2/show/NCT03754309>) was a randomized, double blind, placebo-controlled study of KY1005 in patients with moderate to severe AD conducted

at 20 sites in Europe. Patients were randomized to receive a low dose or high dose of KY1005, or placebo during four visits every 28 days to week 12. The primary endpoints were efficacy as measured by change in the Eczema Area and Severity Index, or EASI, and the incidence of treatment emergent adverse events, or TEAE, from baseline to Week-16. Secondary endpoints included additional assessments of AD including objective clinical measures and patient-reported outcomes related to disease symptoms and quality of life. The trial also assessed PK and PD at several time points. Monitoring of patients is continuing out to 36 weeks since the mechanism of action of KY1005 suggests that it could be disease modifying; results from these further assessments will be available later in 2020. KY1005 has an unremarkable safety profile and is well tolerated as evidenced by the results of a Phase 1 study that completed in March of 2018 and the results from this Phase 2a study. In the Phase 1 clinical trial, (<https://clinicaltrials.gov/ct2/show/NCT03161288>) of 64 healthy volunteers, KY1005 was shown to block T-cell-induced inflammation in the skin.

## **About Atopic Dermatitis and Autoimmune and Inflammatory Disorders**

Immune-mediated and inflammatory disorders (autoimmune diseases) affect up to 50 million Americans, according to the American Autoimmune Related Diseases Association (AARDA). These diseases develop when the immune system, which defends the body against infections, treat healthy cells as foreign. As a result, the immune system attacks healthy cells. An autoimmune disease can affect one or several body tissues and can result in tissue damage, altered growth and impaired organ function, which can be highly painful and debilitating. There are over 80 types of immune-mediated diseases, including Graft-vs-Host Disease, Rheumatoid Arthritis, Psoriasis, Asthma, Atopic Dermatitis, Multiple Sclerosis (MS), Systemic Lupus Erythematosus and Crohn's disease. Currently, treatment for these diseases focuses on dampening or rebalancing the immune system and relieving symptoms because there are no curative therapies.

Atopic Dermatitis, also known as atopic eczema, is the most common chronic inflammatory skin disorder in the developed world and affects around 230 million people globally. Current therapeutic options are limited and there is a lack of truly disease-modifying therapeutics and thus the unmet medical need in this disabling condition remains very high.

## **About Kymab**

Kymab clinical-stage biopharmaceutical company developing fully human monoclonal antibody therapeutics with a focus on immune mediated diseases and immuno-oncology using its proprietary, integrated platforms collectively called IntelliSelect®. Kymab's IntelliSelect Transgenic platforms contain a

full diversity of human antibodies, making them the most comprehensive antibody development platforms available.

Selecting from a broad diversity of fully human antibodies assures the highest probability of finding drug candidates with best-in-class characteristics quickly and efficiently.

For more information on Kymab please see <http://www.kymab.com>. Kymab and IntelliSelect are trademarks of Kymab Limited.

### **Forward-looking statements**

This announcement includes forward-looking statements that involve risks, uncertainties and other factors, many of which are outside of our control, that could cause actual results to differ materially from the results discussed in the forward-looking statements. Forward-looking statements include statements concerning our plans, objectives, goals, future events, performance and/or other information that is not historical information. All such forward-looking statements are expressly qualified by these cautionary statements and any other cautionary statements which may accompany the forward-looking statements. We undertake no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date made, except as required by law.

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