

## **Kymab Announces Promising Results from Initial Clinical Study of New Antibody KY1005 for Treatment of Autoimmune Diseases**

- Top-line Phase I data demonstrated favorable safety, pharmacokinetics and pharmacodynamic properties that support advancement of KY1005 into patient Phase 2 studies
- KY1005, a fully human monoclonal antibody, is an antagonist of OX40-Ligand (OX40L) with the potential to treat a number of immune mediated and inflammatory disorders (autoimmune diseases)
- The study demonstrated an early proof of mechanism of action, as KY1005 was seen to block T-cell-driven inflammation in the skin

**Cambridge, UK; 30 July 2018:** Kymab, a clinical-stage biopharmaceutical company developing fully human monoclonal antibody therapeutics, announces today that it has obtained positive data in its Phase I trial of KY1005 and will proceed to Phase II studies in atopic dermatitis, with additional plans to run studies in other immune-mediated diseases, such as Graft-versus-Host Disease (GvHD).

Results from the Phase I study demonstrate that KY1005 had a favorable safety profile and was well-tolerated. In addition, KY1005 was shown to block T-cell-driven inflammation in the skin of healthy volunteers. The study was a single and multiple ascending-dose, placebo-controlled, double-blind, Phase I study in 64 healthy volunteers.

“KY1005 is an exciting potential therapeutic for several indications and we are delighted to have obtained such encouraging Phase I data, paving the path to further clinical development,” said Dr. Sonia Quaratino, Chief Medical Officer. “With the initial safety and dosing information from this trial, we are now ready to begin dosing atopic dermatitis patients to further assess tolerability and preliminary efficacy.”

KY1005 targets OX40L which, with its receptor OX40, plays a central role in the development of multiple inflammatory and autoimmune diseases, making OX40L blockade an attractive therapeutic option for those diseases maintained by prolonged T-cell responses in which a “resetting” of the immune system is needed.

In its next clinical study, KY1005 will be tested in patients with atopic dermatitis, a condition in which especially high levels of OX40L are found. The Phase IIa trial in atopic dermatitis is expected to begin in late 2018.

Studies in other immune-related diseases, including GvHD, will follow. KY1005 has the potential to transform the outcome of stem cell transplantation through prevention of acute GvHD, acting to inhibit early T-cell expansion post-transplantation. In a study in 2017, KY1005 in combination with sirolimus showed extraordinary efficacy in the prevention of acute GvHD in a non-human primate model of a stem cell transplant (also known as bone marrow transplant), and clinical studies in GvHD are planned for 2019.

###ENDS###

## Notes to Editors

### About OX40/OX40L

OX40 (CD134) and its binding partner, OX40L (CD252), are members of the TNFR/TNF superfamily and are expressed on activated CD4 and CD8 T-cells as well as a number of other lymphoid and non-lymphoid cells. OX40 is activated by its cognate ligand OX40L and functions as a T-cell co-stimulatory molecule. Recent work has suggested that OX40L blockade may be an effective treatment for several forms of autoimmunity.

Levels of OX40L are increased after antigen presentation, to promote division and survival of T-cells and suppress the differentiation and activity of regulatory T-cells. The OX40L/OX40 axis also regulates cytokine production from T-cells, antigen-presenting cells, NK cells and NKT cells, and modulates cytokine receptor signaling. In line with these important modulatory functions, OX40L and OX40 have been found to play a pivotal role in the development of autoimmune diseases, making them attractive candidates for intervention in the clinic.

### About KY1005

KY1005, a fully human monoclonal antibody, is a potential first-in-class therapeutic that may address an underlying immune system imbalance in patients with many autoimmune conditions. It binds to OX40L and blocks it from activating OX40, a protein that induces a prolonged response in T-cells, which can lead to diseases of the immune system and damaging effects on patients. By blocking OX40L from activating OX40, K1005 may act to bring the immune system back into balance. This could lead to a profound clinical impact and restoration of healthy organ functions in autoimmune conditions. Current treatments for these diseases tend to suppress the immune system on a broad basis, leading to significant side effects. One of the potential advantages of KY1005 is that it has the potential to be a more targeted treatment.

### About KY1005 Phase I study

The study was a single and multiple ascending-dose, placebo-controlled, double-blind, Phase I study in 64 healthy volunteers. The study completed on schedule. The first subject first visit took place in June 2017 with last subject visit in March 2018. A protocol amendment was filed in 2017 to allow the study to close after 64 subjects had been treated. This allowed for the early reporting of data and an earlier than expected submission of the Clinical Trial Application for the KY1005 Phase IIa study in atopic dermatitis.

### About Atopic Dermatitis and Immune and Inflammatory Disorders/Autoimmune Diseases

Immune 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. Depending on the type, an autoimmune disease can affect one or many different types of body tissue and can result in tissue damage, altered tissue growth and impaired organ function, which can be highly painful and debilitating. There are over 80 types of immune system diseases, including GvHD, rheumatoid arthritis, psoriasis, atopic dermatitis, multiple sclerosis (MS), lupus and inflammatory bowel diseases (IBD), such as Crohn's

disease and ulcerative colitis. Currently, treatment for these diseases focuses on dampening or rebalancing the immune system and relieving symptoms because there is no curative therapy.

Atopic dermatitis, also known as atopic eczema, is the most common chronic inflammatory skin disorder in the developed world, which 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 a clinical-stage biopharmaceutical company focused on the discovery and development of fully human monoclonal antibody drugs using its proprietary antibody platform which contains a full diversity of human antibodies, making it the most comprehensive antibody development platform available.

Kymab's platform has been designed to maximize the diversity of human antibodies produced in response to immunization with antigens. 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. Kymab is leveraging its platform for its internal drug discovery programs and in partnership with pharmaceutical companies.

For more information please see <http://www.kymab.com>. Kymab is a trademark 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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