



Izana Bioscience's drug namilumab announced in major UK COVID-19 drugs trial

- *First investigational drug selected for testing in innovative CATALYST clinical trial programme in 12 UK centres led by University Hospitals Birmingham, Europe's largest integrated critical care centre*
- *Investigational therapy developed to treat rheumatoid arthritis could be potential therapy for hospitalised COVID-19 patients before intensive care*
- *Monoclonal antibody targets overactive inflammatory response to control 'cytokine storm' and reduce risk of serious lung injury in severe COVID-19 infection*

OXFORD, England, Wednesday June 10, 2020 – Izana Bioscience, the Oxford, UK-based biopharmaceutical company, today announces that its investigational therapy namilumab (IZN-101) has been selected as the first potential treatment to be tested in a new major UK drug trial for hospitalised COVID-19 patients.

The CATALYST trial, running in Birmingham and in close collaboration with Oxford and University College London, will test a series of investigational and already approved drugs. Those that prove successful in CATALYST will be recommended for further testing within large ongoing national trials.

Namilumab, one of four potential treatments in the trial, is a fully human monoclonal antibody already in late-stage trials to treat rheumatoid arthritis. Researchers in Bergamo and Milan, Italy, began in April investigating it as a potential COVID-19 treatment in a compassionate use study.

It targets a cytokine called GM-CSF (granulocyte-macrophage colony stimulating factor), which is naturally secreted by immune cells in the body but, in uncontrolled levels, is believed to be a key driver of the excessive and dangerous lung inflammation seen in COVID-19 patients. The trial will determine whether treating patients with namilumab, before they are admitted to intensive care or require ventilation, can control the overactive inflammatory response known as the 'cytokine storm', reducing the risk of serious lung and other organ injury and eventual death.

Dr Someit Sidhu, Chief Executive and Co-founder of Izana Bioscience, said: *"We are proud to be supporting the CATALYST trial led by the highly experienced team at University Hospital Birmingham, Europe's largest integrated critical care centre. We believe namilumab can play a significant role in dampening the hyper-inflammation seen in patients with severe COVID-19 infection and are committed to working with regulators and partners across the world to ensure this potential therapy can be developed for patients with COVID-19 who urgently need effective treatments."*

Dr Ben Fisher, co-clinical investigator of the CATALYST trial from the University of Birmingham's Institute of Inflammation and Ageing, said: *"There has been a tremendous effort to pull together this initiative so rapidly. Emerging evidence is*

demonstrating a critical role for anti-inflammatory drugs in the cytokine storm associated with severe COVID-19 infection. In the CATALYST study we hope to show with a single dose of these kinds of drugs in hospitalised patients that we are able to delay or prevent the rapid deterioration into intensive care and requirement for invasive ventilation in this critical patient group.”

Ends

About the CATALYST trial

Designed by the Inflammation – Advanced and Cell Therapy Trials Team (I-ACT) at the University of Birmingham’s Cancer Research UK Clinical Trials Unit, the CATALYST trial is being run in close partnership with University Hospitals Birmingham (UHB) and the Birmingham National Institute for Health Research Biomedical Research Centre (NIHR BRC) and delivered in close collaboration with Oxford and University College London NIHR BRC’s.

The trial will compare four treatment options against standard of care, to assess their relative effectiveness against COVID-19 and whether any of the drugs being tested slow disease progression or improve survival. Its adaptive trial design will enable the rapid comparison of the multiple interventions simultaneously, with up to 40 patients recruited to each arm. Patients with COVID-19 will be randomly computer allocated to either receive their usual care or usual care with the addition of one of the trial drugs.

The effect of each drug will be measured by the amount of oxygen in the blood as well as other severity indicators of the disease (i.e. organ failure). Drugs that show reductions in the amount of oxygen needed by the patient and in other severity measures will be recommended for further testing within large ongoing national trials.

About Izana Bioscience

Izana is a translational medicine company focused on bringing innovative science to market. Izana was founded by a team of experienced pharmaceutical industry entrepreneurs and clinicians, led by Dr Someit Sidhu, Chief Executive of Izana Bioscience, and Chairman Professor Bryan Morton CBE. The Company has been initially focused on the development of namilumab in rheumatoid arthritis. Izana is backed by Innovate UK, and Takeda has a strategic equity stake in the Company.

About namilumab (IZN-101)

Namilumab is a human monoclonal antibody targeting granulocyte macrophage-colony stimulating factor (GM-CSF). The antibody has demonstrated efficacy and safety in a phase IIb trial conducted in over 100 rheumatoid arthritis patients, and a phase II proof-of-concept study in ankylosing spondylitis is ongoing. In April 2020 Izana announced a study involving namilumab in the treatment of patients with rapidly worsening COVID-19 in cooperation with the Humanitas research group in Bergamo and Milan, Italy.

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