



**Initiation of two-centre compassionate use study involving namilumab in the treatment of individual patients with rapidly worsening COVID-19 infection in Italy**

- *Emergency access granted to investigational therapy*
- *Objective to treat rapidly deteriorating COVID-19 patients before ICU admission and prior to ventilation*
- *Discussions with international regulators, KOLs and clinical centres of excellence are ongoing to progress namilumab*

OXFORD, England, April 06, 2020 – Izana Bioscience ("Izana" or "the Company"), the Oxford, UK-based biopharmaceutical company focused on the development of namilumab, today announces the initiation of a two-centre compassionate use study involving namilumab (IZN-101) in the treatment of patients with rapidly worsening COVID-19 in cooperation with the Humanitas research group, under the leadership of Professor Carlo Selmi, head of the Rheumatology and Clinical Immunology Unit at Humanitas Research Hospital and Associate Professor of Internal Medicine at Humanitas University. The study will take place in Bergamo and Milan, Italy.

Namilumab is the Company's wholly-owned, phase III-ready, fully human monoclonal antibody therapy targeting granulocyte-macrophage colony stimulating factor (GM-CSF), currently in late-stage clinical development for the treatment of rheumatoid arthritis and ankylosing spondylitis.

GM-CSF is a pro-inflammatory cytokine that plays a central role in a broad range of immune-mediated diseases. The cytokine has been found in higher levels of COVID-19 ICU patients, according to recent data from China<sup>1</sup> suggesting that early intervention could be beneficial in patients with rapidly worsening COVID-19.

The compassionate use programme will gather data from hospitalised, rapidly worsening COVID-19 patients, and has the overall objective of treating them before they are admitted to intensive care or require ventilation.

It also aims to support namilumab's future development for the treatment of COVID-19, and discussions with global regulatory authorities, including the UK, are in progress.

**Dr Someit Sidhu, Chief Executive and Co-founder of Izana Bioscience, said:** *"We are very pleased to be supporting this programme with our anti-GM-CSF mAb, namilumab, for the potential treatment of critically-ill COVID-19 patients. The role of GM-CSF in immune-mediated diseases is backed by a strong body of evidence and our growing understanding of COVID-19. Evidence suggests that anti GM-CSF therapy has the potential to change the way patients' immune systems respond to the virus, and therefore to reduce dangerous inflammation and support recovery."*

**Professor Carlo Selmi, Coordinator of the study and Associate Professor of Internal Medicine at Humanitas University, said:** *"Clinicians working on the frontline urgently require new treatment options for their seriously ill COVID-19 patients. Anti-GM-CSF*

*therapies such as namilumab could play an important role in how we can prevent or reduce the deterioration in COVID-19 patients for which there are currently few treatments available. I am convinced that, even in complicated scenarios such as the current one, it is mandatory to maintain a rigorous scientific approach and in this compassionate use programme we hope to identify patients with a higher inflammatory burden, those we believe are most likely to respond to anti GM-CSF therapy.”*

A number of patients are undergoing COVID-19 treatment at Humanitas and those that are eligible will be entered into the compassionate use programme with namilumab in accordance with local regulations. The team working with Prof. Selmi will be coordinated locally by Dr. Amidio Testa and Dr. Giacomo Guidelli.

Drawing on its rapidly developing experience and expertise in the COVID-19 field, Ergomed plc, a CRO specialised in providing bespoke solutions and research services to the pharmaceutical industry, is facilitating this programme.

### **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<sup>2</sup> conducted in over 100 rheumatoid arthritis patients, and a phase II proof-of-concept study in ankylosing spondylitis is ongoing.

### **References**

1. Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *Lancet*. 2020;395(10223):497-506. doi:10.1016/s0140-6736(20)30183-5.
2. Taylor et al. *Arthritis Research and Therapy* (2019) 21:101

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