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ASIA EDITION

Phase II trial evaluating Kevzara looks promising to fight COVID-19

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The study involves testing a variety of severity groups to understand the relationship between the cytokine response in COVID-19 patients



Regeneron and Sanofi recently announced the preliminary results from the Phase II portion of an ongoing Phase II/III trial evaluating Kevzara (sarilumab), an antibody targeting the interleukin-6 (IL-6) receptor, in hospitalized patients with severe or critical respiratory illness caused by COVID-19.

Angad Lotay MPharm, Infectious Diseases Analyst at GlobalData, comments: “Targeting the correct patient population and severity group is vital when conducting any study. However, testing a variety of severity groups in this trial allowed a process of elimination to help understand the relationship between the cytokine response in COVID-19 patients, and more importantly of when to treat with IL-6 inhibitors (or in this case, when not to treat). In order to draw more conclusive evidence, Sanofi and Regeneron are proceeding with its phase III portion of Phase II/III trial, specifically targeting critically ill patients at a dose of 400mg. This will provide a more accurate demonstration as to whether there is a relationship between the use of IL-6 modulators and the most severe COVID-19 patients”.

COVID-19 can lead to a cytokine response syndrome (CRS), and its management follows a grade and risk-adapted strategy. Low-grade CRS is treated symptomatically with antihistamines, antipyretics, and fluids, whereas more severe patients require ventilator support due to life-threatening symptoms. Not all patients with CRS will require intensive care. It is therefore important to identify suitable candidates who are most likely to benefit from inhibiting IL-6, which is a central driver for many symptoms of CRS.

Lotay continues: “Although it is known that IL-6 is a key cytokine mediator in CRS, its onset and peak timing can vary in different diseases. It is important to evaluate the relationship between the peak level and time of serum cytokines to ultimately optimize treatment timing. Sanofi and Regeneron now have some data on that, and the results of the Phase III Kevzara trial will provide a better understanding this pattern in COVID-19 patients.”