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Roche's Actemra drug fails in Ph III COVACTA trial for COVID-19

30 July 2020 | News

COVACTA trial did not meet its primary endpoint of improved clinical status in patients with COVID-19 associated pneumonia, or the key secondary endpoint of reduced patient mortality

Swiss firm Roche has announced that the phase III COVACTA study of Actemra®/RoActemra® (tocilizumab) did not meet its primary endpoint of improved clinical status in hospitalised adult patients with severe COVID-19 associated pneumonia.

In addition, the key secondary endpoints, which included the difference in patient mortality at week four, were not met; however, there was a positive trend in time to hospital discharge in patients treated with Actemra/RoActemra.

The COVACTA study did not identify any new safety signals for Actemra/RoActemra. Further analysis of the trial results is needed to fully understand the data. The results will be submitted for publication in a peer-reviewed journal.

The COVACTA trial was conducted in collaboration with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the United States Department of Health and Human Services.

“People around the world are waiting for further effective treatment options for COVID-19 and we are disappointed that COVACTA did not demonstrate a benefit for patients in either clinical status or mortality at week four. We will continue to generate evidence to provide a more complete understanding of Actemra/RoActemra in COVID-19 associated pneumonia,” said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. “We are grateful for the patients and physicians around the world who helped us to complete this study quickly during a public health crisis, while upholding the highest standards of scientific rigour. We will keep working to help combat the COVID-19 pandemic."

In addition to COVACTA, Roche has initiated several studies to further investigate Actemra/RoActemra as a potential treatment for patients with COVID-19 associated pneumonia, including two phase III clinical trials, REMDACTA and EMPACTA, as well as the phase II MARIPOSA trial. There are also a number of independent trials of Actemra/RoActemra in this setting. Actemra/RoActemra has not previously been studied in, nor approved for, COVID-19 associated pneumonia.