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ASIA EDITION

Korea's Celltrion receives US FDA approval of expanded indication for AVTOZMA

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An intravenous (IV) formulation in cytokine release syndrome (CRS)

South Korea-based Celltrion, Inc. has announced that the US Food and Drug Administration (FDA) has approved an expanded indication of the intravenous (IV) formulation of AVTOZMA® (tocilizumab-anoh) to include the treatment of cytokine release syndrome (CRS) in adults and pediatric patients aged 2 years and older.

Following FDA approval of the additional indication for CRS, AVTOZMA IV now aligns with all indications approved for ACTEMRA® IV in the United States.

Earlier this year, the US FDA approved AVTOZMA as a biosimilar to ACTEMRA in IV formulations for the treatment of multiple diseases including rheumatoid arthritis (RA), giant cell arteritis (GCA), polyarticular juvenile idiopathic arthritis (pJIA), systemic juvenile idiopathic arthritis (sJIA) and coronavirus disease (COVID-19).

CRS is a potentially life-threatening condition that occurs when the immune system is highly activated, leading to the rapid and excessive release of cytokines into the bloodstream.

AVTOZMA® (tocilizumab-anoh), containing the active ingredient tocilizumab, is a recombinant humanised monoclonal antibody that acts as an interleukin 6 (IL-6) receptor antagonist.