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India gives nod to use of inhaled Ampion for COVID-19-related respiratory distress

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Ampio Pharma receives approval to commence AP-019 Ph II study in India

US-based Ampio Pharmaceuticals has announced regulatory approval from the Drugs Controller General of India (DCGI) of the Central Drugs Standard Control Organization (CDSCO) in the Phase II AP-019 clinical trial in India.

The study will utilize inhaled Ampion™ to treat those suffering from respiratory distress due to COVID-19.

Following presentation of Ampion to a Subject Expert Committee (SEC) established by the DCGI, the AP-019 treatment protocol was approved with no recommended changes.

As an immunomodulatory agent with anti-inflammatory effects, Ampion interrupts the hyperactive immune response associated with COVID-19 and, as such, may improve the clinical outcome for patients suffering from its complications. Directly administering Ampion to patients by inhalation allows the drug to directly target and attenuate inflammation in the lungs.