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DCGI approves 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 utilise inhaled Ampion to treat those suffering from respiratory distress due to COVID-19.

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

The company initiated the AP-019, double-blind, placebo-controlled Phase II trial, utilizing inhaled Ampion following the strong top-line results achieved from its AP-014 Phase I trial. On April 27, 2021, the company reported the earlier Phase I study not only met its primary endpoint of safety and tolerability, but top-line results also showed that Ampion reduced all-cause mortality in COVID-19 respiratory distress by 78 per cent over the Standard of Care (SOC) for patients suffering from respiratory distress due to COVID-19. Specifically, mortality in the SOC group was 24 per cent, while in the group treated with SOC and Ampion, mortality was only 5 per cent.