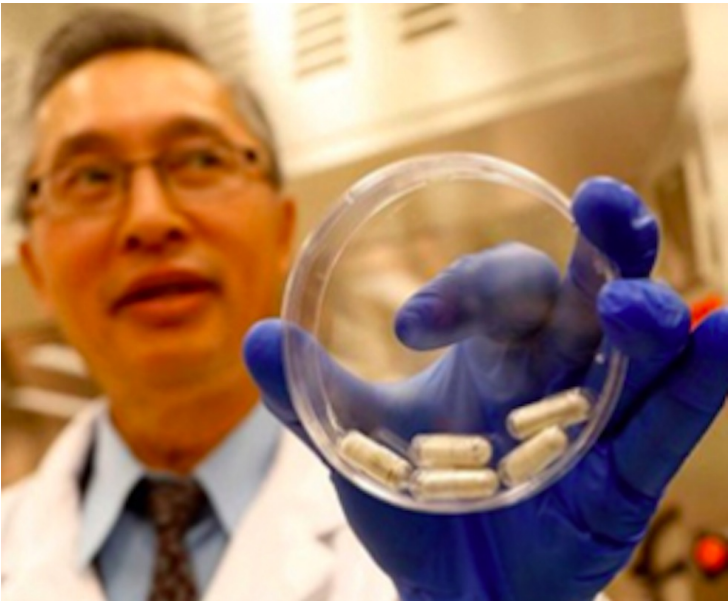


Favipiravir significantly improving clinical cure in COVID-19 patients

24 November 2020 | News

These findings were observed in a randomised, controlled Phase 3 clinical study conducted by Glenmark Pharmaceuticals



The oral antiviral medication Favipiravir, that prevents the replication phase of the virus life-cycle, leads to significant improvement in clinical cure in patients with mild to moderate COVID-19. These findings were observed in a randomised, controlled Phase 3 clinical study conducted by Glenmark Pharmaceuticals, and the results are now published online in The International Journal of Infectious Diseases (IJID). The IJID is a globally reputed, peer-reviewed, pubmed indexed, open access journal published monthly by the International Society for Infectious Diseases, US.

The Phase 3 study with antiviral drug Favipiravir, brand name FabiFlu®, was conducted in 150 patients as part of a randomised, open label, multicentre, Phase 3 study. The study aimed to evaluate the efficacy and safety of Favipiravir plus standard supportive care (Favipiravir treatment arm), versus standard supportive care alone (control arm), in mild to moderate patients, randomised within a 48 hour window of testing RT-PCR positive for COVID-19.

Favipiravir was found to provide multiple treatment benefits, demonstrated by faster time to clinical cure, and significantly delayed the need for supportive oxygen therapy. Additionally, patients of confirmed COVID-19 with moderate symptoms were discharged from hospital earlier than those patients that did not receive Favipiravir, with the median time to clinical cure reduced by 2.5 days compared with the control group.

Robert Crockett, Chief Commercial Officer, Glenmark Pharmaceuticals, said, "It is encouraging to see our trial results now published in a reputed global medical journal, which we hope will support other countries in their fight against this disease."

Patients in the Glenmark clinical trial received Favipiravir tablets 3,600 mg (1,800 mg BID) (Day 1) + 1,600 mg (800 mg BID) (Day 2 or later) for up to maximum of 14 days, along with standard supportive care. Randomisation was stratified based on

disease severity into mild and moderate. Favipiravir was well tolerated with no serious adverse events (SAEs) or deaths in the Favipiravir treated arm.

The pre-specified primary endpoint, time from randomisation to cessation of oral shedding of the SARS-CoV-2 virus, demonstrated a two day earlier virological cure in the Favipiravir treatment group, though not statistically significant. However, significant improvement in time to clinical cure and other secondary end-points suggest Favipiravir may be beneficial in the treatment of mild-to-moderate COVID-19.