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Frontier Biotechnologies proposes treatments for acute and prolonged COVID

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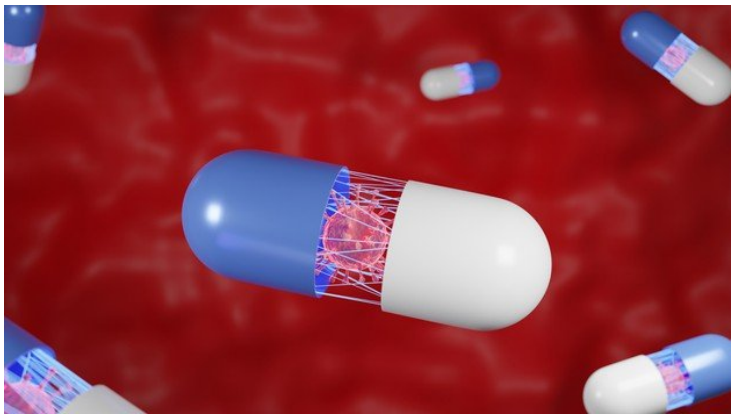
Announces Positive Phase 1 results of its first Coronavirus Main Protease (Mpro) Small Molecule Inhibitor



China-headquartered global biopharmaceutical company Frontier Biotechnologies announced positive results from the Phase 1 clinical trial of its drug candidate, FB2001 – a small molecule inhibitor of coronavirus main protease (M^{pro}) – in healthy adult volunteers.

The data, presented at the poster session of the 11th International Conference on Emerging Infectious Diseases (ICEID), showed FB2001 to be safe and well tolerated among trial participants. Adverse events reported during the trial were mostly mild-to-moderate in severity, with no significant differences observed between participants in the Chinese and American study centers.

The key findings from the study are as follows:

- FB2001 was safe and well tolerated up to 400 mg per day
- Without using a pharmacokinetic enhancer, FB2001 exhibited plasma and lung drug concentration above the *in vitro* antiviral EC_{50} value.
- No significant difference was observed between Chinese and American populations.

“FB2001 has demonstrated *in vivo* antiviral activity in the lung and brain tissue of SARS-CoV-2 mouse model without the need for pharmacokinetic boosting. Therefore, it holds great promise as a treatment for acute COVID-19 as well as long-COVID, both of which will be evaluated in further follow-up studies”, said Dr Jay Lalezari, MD, Medical Director of Quest Clinical Research in San Francisco.

Frontier Biotechnologies is also developing a pulmonary formulation of FB2001 that could be used in out-patient setting for the treatment of mild Covid-19, as well as for post-exposure prophylaxis. When inhaled directly into the respiratory tract and lungs, the tissue concentration of FB2001 is much higher than that in plasma; hence, the onset of action and viral clearance could potentially be faster than that of oral therapy**.**