

PNB Vesper gets DCGI nod to conduct Ph III trials on COVID-19 drug

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According to the company, PNB 001/ GPP-BALACOVIN is proving to be a breakthrough in COVID-19 treatment



Kerala-based pharmaceutical organization PNB Vesper has received DCGI permission to conduct the final phase 3 clinical trials. After a detailed deliberation by the Subject Expert Committee (SEC) on the Phase 2 Clinical Trial results of PNB-001 (GPP-BALACOVIN), the company has now been given a green signal to conduct a nationwide multi-centred Phase 3 Clinical Trial on hospitalised COVID-19 patients with oxygen support.

The Phase 3 trial will be conducted on a large patient population in 12 hospitals all over India. GPP- BALACOVIN is a novel and safe drug that possesses significant efficacy to save the hospitalised patients with oxygen support, from the deadly coronavirus.

PN Balam, CEO, PNB Vesper Life Sciences said, "We are happy that we have successfully developed a New Chemical Entity to treat COVID-19 and have received approval from DCGI to conduct the Phase 3 Clinical trials. This is a promising drug for COVID-19 patients around the world, who are hospitalised with oxygen support. The drug is explicitly non-toxic to humans as evidenced in Phase 1 and Phase 2 clinical trials. None of the patients treated with GPP- BALACOVIN reported any post-treatment health risks. There are about 28 post-covid long-term complications identified by WHO and our treated group does not pose any such long-term health risks and is feeling healthy compared to the standard arm."

Dr Eric Lattman, Vice President, PNB Vesper said, "The performance of GPP- BALACOVIN is much superior over the current treatment paradigm. The mechanism of action of the drug is unique and innovative. The parameters evaluated in the clinical trial indicates the potential of the drug in treating COVID-19 patients. The results of the clinical trial indicate that GPP- BALACOVIN was found to be a turbo anti-inflammatory molecule with immuno-modulation properties. This breakthrough feature of GPP- BALACOVIN can help in the treatment of several acute inflammatory and auto-immune diseases and cancer treatments in the future."