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PNB Vesper receives DCGI approval to test NCE PNB 001 in COVID-19 patients

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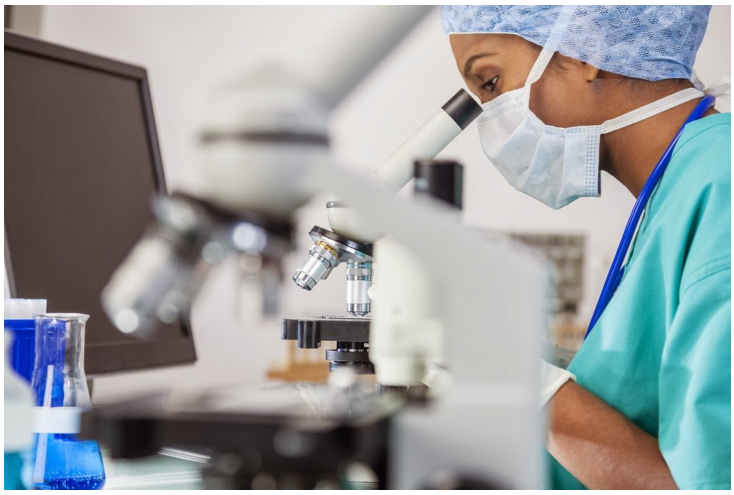
A breakthrough innovation in COVID-19 treatment from India to the world



PNB Vesper in Kochi has received approval from the Drug Controller General of India (DCGI) to conduct the Phase 2b Clinical trial of their propriety drug PNB-001 (GPP-Baladol®) in testing COVID-19 patients.

PNB 001 may be the first New Chemical Entity (NCE) in the world for testing in COVID-19 patients. The company has filed the Clinical trial application with DCGI for the Phase 2 Clinical Trials and the study will be completed in 60 days. The study will be conducted in 40 Covid-19 positive patients at BMJ Medical College, Pune who are moderate patients on oxygen support.

The effect of PNB 001 will be compared with DEXAMETHASONE, currently the most popular medicine in COVID-19 treatment in the world. A larger population, approximately 350 Covid-19 patients will be enrolled Across the Country in 6 medical Colleges the Phase 3 Clinical trials after reviewing the phase 2 clinical trial results. The molecule has already been patented and the related Intellectual Property Rights (IPRs) have been secured by PNB VESPER in the US, Europe and rest of the world.

As per the human Studies, GPP Baladol® (PNB-001) was found extremely safe in a PHASE 1 clinical trials with expected pharmacokinetics, and Pharmacodynamics leading to subsequent phase 2b /3 trials. It was tested in 74 healthy subjects at low, medium and high doses over a course of various periods. In the pre-clinical models, PNB-001 was found to be highly effective in inflammation compared with Steroids. It was also found PNB 001 is twenty times more potent than Aspirin which is the gold standard for Pyrexia Studies.

Further, the US FDA has shown interest in the drug and the discussions with USFDA are in the final stages. Other than this, discussions have already been initiated with the UK Government to include PNB 001 in the ongoing COVID 19 clinical trials. PNB Vesper's UK Scientific Team headed by Dr. Eric Lattmann is coordinating the UK developments.

Highlighting the key findings of PNB – 001, Dr. Eric Lattmann, Vice President Research PNB VESPER said, "PNB-001 has been found to be twenty times more efficacious than Aspirin in the Antipyretic and Pain Studies. It has shown remarkable

results in lung inflammation and ARDS (Acute Respiratory Distress Syndrome). In the Dengue Virus Viremia Model studies, PNB 001 reduced the mortality of animals significantly, almost 80% than the control group. It is also proved that the Cytokine storms and Spleen size reduced significantly. This means the mortality rate can be reduced considerably by using GPP Baladol".

Speaking on the breakthrough innovation, P N Balaram, CEO of PNB Vesper Life Pvt Ltd said, "This is indeed a very big step for mankind in its fight against the Covid-19 pandemic. Post the DCGI Permission, our initial clinical trials would be completed in 60 days. Considering the novel mechanism of our molecule, we expect much better results in the clinical trials compared with Dexamethasone. In COVID-19, the main symptoms are Pyrexia, Body Pain and inflammation in the Lung and we lose patients mainly because of Cytokine Storms and ARDS. We have proved in the pre-clinical studies our drug is effective in reducing fever, body pain and inflammation. The drug GPP – Baladol has shown positive results in all the initial pre-clinical studies and we do hope that the final trials would prove the efficacy of the molecule in COVID-19 patients, which could lead to the manufacturing of the drug. PNB 001 is further found to be very effective in Small Cell Lung Cancer Xenograft and Allograft studies too. If the molecule is found to work successfully in Covid-19 patients, PNB 001 may be the first new Chemical Entity in the world for COVID-19 treatment."

PNB Vesper has 6 molecules in various development stages targeting treatment for a number of health problems:

- A CCK_2 antagonist, is under development for the treatment of inflammatory pain, Arthritis and inflammatory bowel disease is in the phase 2 clinical trials. The clinical results will come out before September end 2020.
- PNB-028, a CCK isoform-selective antagonist is being developed for the treatment Pancreatic and Colon cancer is in the phase 2 a Clinical trials. The initial clinical studies will be completed before March 2021
- PNB-081, a CK_1 antagonist for the treatment of pain in conjunction with opioids and Pancreatitis is in the IND studies
- PNB-291 is in the Regulatory IND stage studies for neuroendocrine cancers ,Brain and Tripple resistant Breast Cancers
- PNB 291 found to be 20 times efficacious than TAMAZOLOMIDE and BCNU , the existing Brain Cancer molecules in the world in the Xenograft and Alograft studies.
- PNB – 102 for Gastric Cancer and Small Cell Lung Cancer.