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India-made prostate cancer drug files for IND with FDA

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Bangalore: A new drug to treat prostate cancer, which was developed by Bangalore-based Jubilant Biosys and US-based collaborator Endo Pharmaceuticals, has crossed a major milestone, with the US FDA accepting its application to treat it as a novel molecule.

Jubilant Biosys revealed that the US FDA has accepted the investigational new drug (IND) filing application, which is the first regulatory stage of acceptance of the potential of the new molecule, and that the clinical trials of the product will start later this year.

Both the companies started working on the development of this new molecule three years ago. The IND filing will take the product to the next stage of development and is a major progress in drug development.
"We are pleased and elated with this successful outcome, which is the result of excellent collaboration between the scientists at Endo and Jubilant Biosys," said Dr Subir Kumar Basak, president, global drug discovery services, Jubilant Life Sciences.

"I congratulate the Jubilant and Endo teams on achieving this important milestone," said Dr Sandeep Gupta, senior VP, Endo Pharamceuticals." This further validates Endo's unique collaborative drug discovery approach which aims at unmet medical needs and improves patient outcomes."

Prostate cancer is the second most reported form of cancer in the US and many other countries. New drug development in this field is going on strongly and at least 333 companies with their partners are currently working on developing 402 drugs to treat prostate cancer.