Reliance Life Sciences appeals marketing restrictions on breast cancer drug

Synopsis
The counsel is appealing conditions including the restrictions placed on the labelling of TrastuRel as well as those placed on using Roche's data.

NEW DELHI: After **Biocon and Mylan**, **Reliance Life Sciences** has approached the **Delhi High Court** to appeal against an earlier order that imposed marketing restrictions to its copy of Swiss biotech giant **Roche**'s **breast cancer drug**, Herclon (trastuzumab).

After Reliance was prevented from launching its product, **TrastuRel**, in November, an April 25 court judgement finally allowed the company to introduce its product along with restrictions similar to the ones imposed on Biocon's CANMAb and Mylan's Hertraz.

The judgement, given by Justice **Manmohan Singh**, directed that Reliance could manufacture, market and advertise TrastuRel without calling it a "bio similar" or in any way ascribing biosimilarity to inventor, Roche's products—Herceptin, Herclon and Biceltis.

The company's appeal will be heard along with **Biocon** NSE -1.31 % and Mylan's by Justices Badar Durrez Ahmed and Sanjeev Sachdeva on July 21, 2016. The judges have called on Roche's subsidiary, Genentech, for a response in the meantime.

Reliance's appeal is distinct from Biocon and Mylan's, argued Reliance Life Sciences counsel **Pratibha Singh** at court on June 3. Reliance was given an injunction before it had launched TrastuRel, whereas CANMAb and Hertraz were already in the market when Roche sued them, she told judges.

The counsel is appealing conditions including restrictions placed on TrastuRel labelling as well as those on using Roche's data, according to Singh.

The April 25 judgement stated that Reliance could also manufacture and market the drug by qualifying the International Non-proprietary Name (INN)

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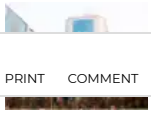

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Bharat Bio hopes to soon submit trial data for intranasal vaccine

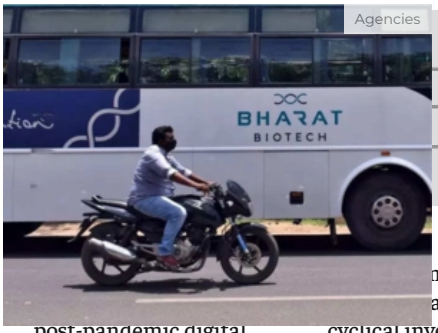
By Teena Thacker, ET Bureau Last Updated: Oct 14, 2021, 07:15 AM IST

Synopsis

"The trials are ongoing, and we expect to submit data by the end of this year," a company insider said. The trials, including over 600 participants, are being conducted by dividing the volunteers into three groups.

After receiving po ations from the expert committee on **Covaxin** use for c iotech is now looking to submit the trial results of its Covi accine by end of this year, people in the know told ET.

"The trials are ongoing, and we expect to submit data by the end of this year," a



The first group is administered Covaxin as the first dose and intranasal vaccine as the second dose. The second group will get both doses in the form of intranasal vaccine.

The third group will get the intranasal vaccine as the first dose and Covaxin jab as the second dose. The doses are given 28 days apart. The intranasal vaccine can be game changer in the vaccination drive because it offers the convenience of administration.

The drug regulatory authority had in August given its approval to Hyderabad-based Bharat Biotech to conduct phase-2/3 trials on its intranasal vaccine.

The adenoviral intranasal vaccine BBV154 is the first of its kind Covid-19 jab which has been undergoing human trials in India. The phase-1 trial in healthy volunteers of age groups ranging from 18 to 60 years was well tolerated, the ministry of science and technology said in a statement earlier.

It also said the vaccine was found to be safe, immunogenic and well-tolerated in the preclinical toxicity studies and was able to elicit high levels of neutralizing antibodies in animal studies.

The development of Bharat Biotech's intranasal vaccine has been supported by the department of biotechnology (DBT) and Biotechnology Industry Research Assistance Council (BIRAC). The company strategised to fast-track research and development efforts, especially for vaccine development, diagnostics, drug repurposing, therapeutics and testing.

Bharat Biotech's (onstrated 77.8% efficacy against symptomatic Cov gainst severe illness during the phase-3 clinical trials.

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