PRESS NOTE

Bedaquiline (BDQ)

Drug resistant TB is a major concern for the World and so for India as the country is facing the serious issue of multi drug resistant patients. The usual treatment options available for this resistant type of disease comprise of a minimum of 20 months of treatment with drugs which are toxic, very expensive and much less effective. Treatment success with these drugs globally and in India is just 50%. This success rate further falls in situations where there is resistant to other drugs such as injections and fluoroquinolones.

In an effort to change this scenario, researchers have been working on the global TB drug pipeline and as a consequence of research, Jansen scientists discovered and developed a drug Bedaquiline (BDQ). At present, this drug is manufactured and marketed by Jansen & Jansen under the trade name of Sirturo. Research on this drug started in 1997 and after having proven its efficacy and safety in a limited number of patients, the Phase-III trials started in 2013. As mandated by the Drug Regulatory Authority before any drug is approved for sale and use; it needs to have successfully completed Phase-III trials. However, due to the urgent need of MDR-TB patients and poor outcomes with the usual drugs; BDQ was accorded accelerated approval by the US Drug Regulatory Authority. Consequently, the World Health Organization gave the technical guidance for its use in such patients in the year 2013. Government of India has developed guidelines for use of Bedaquilline in India under Revised National TB Control Programme. The drug has potential for serious adverse affects on the heart and the liver and may lead to even death. Hence, before this drug is to be used, the guidelines need to be followed strictly for identifying the patients who would benefit and ensuring close monitoring and supervision during treatment for adverse drug reactions.

India brought the drug into use in 2016 under the Conditional Access Programme (CAP) following strict enrolment criteria and close monitoring in view of the severe forms of Adverse Drug Reactions and even death which could occur with this drug. At present, the drug is available through the Government mechanism of CAP in six sites in the country and it is envisioned to extend it to the entire country within this year. The trainings for the health providers which are mandatory before using the drug, are already being conducted at different sites of the country in Delhi, Mumbai, Guwahati, Chennai, Ahmedabad. Programme is making necessary preparation and arrangements to make this drug available across the country by the end of year 2017.

For patients being treated outside the Government system, the manufacturers are providing this drug under Compassionate Use Programme free of cost to the doctors provided they follow the recommended guidelines for starting the drug and its close monitoring. Compassionate use refers to the use outside of a clinical trial of an investigational medical product (i.e., one that has not been approved by Drug Controller/Competent Authority. Under this protocol, a Medical practitioner can prescribe such medicine to needy patients.