Zydus receives final approval from the USFDA for Bosentan Tablets & Trientine Hydrochloride Capsules

Ahmedabad, 30 April, 2019

Zydus Cadila has received the final approval from the USFDA to market Bosentan Tablets USP (US RLD – Tracleer® Tablets), 62.5 mg and 125 mg and Trientine Hydrochloride Capsules USP (US RLD - Syprine® Capsules), 250 mg. Both the products will be manufactured at the group's formulations manufacturing facility at SEZ, Ahmedabad.

Bosentan is used to treat high blood pressure in the lungs (pulmonary arterial hypertension). This condition is thought to be caused by increased levels of a certain natural substance (endothelin-1). This medication blocks the effects of endothelin-1, which helps lower blood pressure in the lungs, slow the worsening of symptoms from the disease and improves ability to exercise.

Trientine is a chelating agent. It works by removing a heavy metal (copper) from the blood. It is used to treat the Wilson's disease, a genetic metabolic defect that causes excess copper to build up in the body. Trientine is used to treat this inherited condition in people who cannot take penicillamine.

The group now has 265 approvals and has so far filed over 350 ANDAs since the commencement of the filing process in FY 2003-04.

About Zydus Cadila

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies. The group employs over 23,000 people worldwide and is dedicated to creating healthier communities globally. Zydus aspires to be a research-based pharmaceutical company by 2020.

***