Zydus receives final approval from USFDA for Apalutamide Tablets, 60 mg

Ahmedabad, India, 18 March, 2025

Zydus Lifesciences Limited (including its subsidiaries/ affiliates, hereafter referred to as "Zydus") has received final approval from the United States Food and Drug Administration (USFDA) to manufacture Apalutamide Tablets, 60 mg (Erleada® Tablets, 60 mg).

Apalutamide is an androgen receptor inhibitor indicated for the treatment of patients with metastatic castration-sensitive prostate cancer. Apalutamide tablets will be produced at Zydus Lifesciences Ltd (SEZ), Ahmedabad.

Apalutamide tablets had annual sales of USD 1099.8 mn in the United States (IQVIA MAT January 2025).

The group now has 420 approvals and has so far filed 483* ANDAs since the commencement of the filing process in FY 2003-04.

*(*As on 31st December, 2024.)*

PRESS RELEASE

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited
Regd. Office : 'Zydus Corporate Park',
Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar),
Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382
481, Gujarat, India. | Phone : +91-79-71800000,
+91-79-48040000 | website : www.zyduslife.com
CIN : L24230GJ1995PLC025878