Date: 1st January, 2024

To,
The Manager,
Department of Corporate Services,
BSE Limited
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001
BSE Scrip Code: 533573

To,
The Manager,
Listing Department,
National Stock Exchange of India Ltd.
'Exchange Plaza', Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051
NSE Symbol: APLLTD

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals receives various US Food & Drug Administration (USFDA) product approvals (Tentative or Final) during the quarter ended 31st December, 2023.

With reference the captioned subject, this is to inform the exchange that the Company has received various US Food & Drug Administration (USFDA) Product Approvals (Tentative or Final) during the quarter ended 31st December, 2023.

The summary statement giving brief of all product approvals received during the quarter ended 31st December, 2023 is enclosed for your information and records.

Alembic has a cumulative total of 196 ANDA approvals (170 final approvals and 26 tentative approvals) from USFDA.

We request you to kindly take the above on record.

Thanking you,

Yours faithfully,
For Alembic Pharmaceuticals Limited

MANISHA SARAF Digitally signed by MANISHA SARAF
Date: 2024.01.01 18:58:00 +05'30'

Manisha Saraf
Company Secretary

Encl: A/a.

Annexure

Summarised Product Approval(s) received during the quarter ended 31st December, 2023.

Product Name	Approval Final/ Tentative	Innovator Name	Brand name	Indication*
Selexipag Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,400 mcg and 1,600 mcg.	Final	Actelion Pharmaceuticals US, Inc.	Uptravi Tablets	Selexipag tablets are indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH.
Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg, and 20 mg.	Tentative	Janssen Pharmaceuticals, Inc.	Xarelto Tablets	Rivaroxaban tablets are indicated - I) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. II) for the treatment of deep vein thrombosis (DVT). III) for the treatment of pulmonary embolism (PE). IV) for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months. V) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery. VI)for the prophylaxis of venous thromboembolism (VTE) and VTE related

Product Name	Approval Final/ Tentative	Innovator Name	Brand name	Indication*
				death during hospitalization and post hospital discharge in adult patients admitted for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE and not at high risk of bleeding. VII), in combination with aspirin, is indicated to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI) and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD).
Dapsone gel, 7.5%	Final	Almirall, LLC	Aczone Gel	Dapsone gel, 7.5% is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.
Bromfenac Ophthalmic Solution, 0.07%.	Tentative	Bausch & Lomb Incorporated.	Prolensa Ophthalmic Solution	Bromfenac ophthalmic solution 0.07% is indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

Product Name	Approval Final/ Tentative	Innovator Name	Brand name	Indication*
Fluorouracil Injection USP, 5 g/100 mL (50 mg/mL), Pharmacy Bulk Package (Vial).	Final	Pharmcia and Upjohn	Adrucil Injection USP	Fluorouracil is a nucleoside metabolic inhibitor indicated for the treatment of patients with- • Adenocarcinoma of the Colon and Rectum • Adenocarcinoma of the Breast • Gastric Adenocarcinoma • Pancreatic Adenocarcinoma
Carmustine for Injection USP, 100 mg/vial (Single-dose Vial).	Final	Avet Lifesciences Private Limited	BiCNU Injection	Carmustine for injection is indicated as palliative therapy as a single agent or in established combination therapy in the following: - Brain tumors glioblastoma, brainstem glioma, medulloblastoma, astrocytoma, ependymoma, and metastatic brain tumors. - Multiple myeloma in combination with prednisone. - Relapsed or refractory Hodgkin's lymphoma in combination with other approved drugs. - Relapsed or refractory Non-Hodgkin's lymphomas in combination with other approved drugs.

Product Name	Approval Final/ Tentative	Innovator Name	Brand name	Indication*
Acyclovir Cream, 5%,	Final	Bausch Health US, LLC	Zovirax Cream	Acyclovir cream, 5% is a herpes simplex virus (HSV) deoxynucleoside analogue DNA polymerase inhibitor indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults and adolescents 12 years of age and older.
Osimertinib Tablets, 40 mg, and 80 mg.	Tentative	AstraZeneca Pharmaceuticals LP	Tagrisso Tablets	Osimertinib tablets are indicated for -the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. - the treatment of patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.

*Refer label for full indication.