

Date: 10<sup>th</sup> January, 2022

To,  
The Manager,  
Department of Corporate Services,  
BSE Limited  
P. J. Tower, Dalal Street,  
Fort, Mumbai – 400 001

Dear Sir/Madam,

**Sub: Alembic Pharmaceuticals Limited receives USFDA Tentative Approval for Dronedarone Tablets USP, 400 mg.**

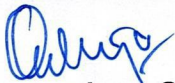
With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Tentative Approval for Dronedarone Tablets USP, 400 mg.

Please find enclosed herewith our press release.

We request you to kindly take the same on record.

Thanking you,

Yours faithfully,  
**For Alembic Pharmaceuticals Limited**



**Charandeep Singh Saluja**  
Company Secretary

Encl.: A/a.



## PRESS RELEASE

10<sup>th</sup> January, 2022, Vadodara, India

### **Alembic Pharmaceuticals receives USFDA Tentative Approval for Dronedarone Tablets USP, 400 mg.**

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Dronedarone Tablets USP, 400 mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Multaq Tablets, 400 mg, of Sanofi-Aventis U.S. LLC (Sanofi-Aventis). Dronedarone is indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation.

Dronedarone Tablets USP, 400 mg have an estimated market size of US\$ 500 million for twelve months ending September 2021 according to IQVIA. Alembic has settled the case with Sanofi-Aventis and will launch its generic as per the terms of settlement.

Alembic has received year to date (YTD) 19 approvals (13 final approvals and 6 tentative approvals) and a cumulative total of 158 ANDA approvals (136 final approvals and 22 tentative approvals) from USFDA.

### **About Alembic Pharmaceuticals Limited**

Alembic Pharmaceuticals Limited, a vertically integrated research and development pharmaceutical company, has been at the forefront of healthcare since 1907. Headquartered in India, Alembic is a publicly listed company that manufactures and markets generic pharmaceutical products all over the world. Alembic's state of the art research and manufacturing facilities are approved by regulatory authorities of many developed countries including the USFDA. Alembic is one of the leaders in branded generics in India. Alembic's brands, marketed through a marketing team of over 5000 are well recognized by doctors and patients.

Information about Alembic can be found at <http://www.alembicpharmaceuticals.com/>; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

For more information contact:

Ajay Kumar Desai	Mitanshu Shah
Phone: +91 22 - 306 11681	Phone: +91 265 - 6637630
Email: <a href="mailto:ajay.desai@alembic.co.in">ajay.desai@alembic.co.in</a>	Email: <a href="mailto:mitanshu.shah@alembic.co.in">mitanshu.shah@alembic.co.in</a>



### **ALEMBIC PHARMACEUTICALS LIMITED**

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003. • TEL : (0265) 2280550, 2280880 • FAX : (0265) 2281229  
website : [www.alembicpharmaceuticals.com](http://www.alembicpharmaceuticals.com) • E-mail : [alembic@alembic.co.in](mailto:alembic@alembic.co.in) • CIN : L24230GJ2010PLC061123