Press Release by Rhizen

Rhizen Pharmaceuticals AG Announces that its Partnered Asset, Umbralisib (UKONIQ™), has Received US FDA Accelerated Approval for Adult Patients with Relapsed or Refractory MZL & FL

- **Umbralisib (UKONIQ™) granted accelerated approval by US FDA for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL), follicular lymphoma (FL).**
- **Umbralisib, a novel next generation inhibitor of PI3K delta & CK1 epsilon, was discovered by Rhizen Pharmaceuticals and subsequently licensed to TG Therapeutics, who led the asset's clinical development.**
- **Rhizen and its affiliate Alembic Pharma to support TG Therapeutics towards UKONIQ's commercialization as its manufacturing & supply partner; Rhizen plans to register and commercialize Umbralisib in India.**

February 08, 2021 – Basel, Switzerland: Rhizen Pharmaceuticals, a clinical-stage oncology-focused biopharmaceutical company, today announced that its novel next generation PI3K-delta inhibitor, Umbralisib, which was licensed to TG Therapeutics (NASDAQ: TGTX), has secured US FDA accelerated approval for the treatment of:

- adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20 based regimen, and
- adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy.

Accelerated approval was granted for these indications, under a priority review (MZL), based on the results of the Phase 2 UNITY-NHL Trial (NCT02793583); in MZL, an ORR of 49% with 16% complete responses and in FL an ORR of 43% with 3% complete responses were achieved, respectively. Umbralisib was earlier granted Breakthrough Therapy Designation (BTD) for the treatment of MZL and orphan drug designation (ODD) for the treatment of MZL and FL.

Umbralisib is a novel, next generation, oral, once daily, inhibitor of phosphoinositide 3 kinase (PI3K) delta and casein kinase 1 (CK1) epsilon and and was discovered by Rhizen Pharma and subsequently licensed to TG Therapeutics (NASDAQ: TGTX) at an IND stage (TGR 1202) in 2012. In 2014, both parties entered into a licensing agreement as a part of which TGTX obtained worldwide rights and Rhizen has retained commercialization rights for India while also being the manufacturing and supply partner for Umbralisib.

Swaroop Vakkalanka, President & CEO of Rhizen Pharmaceuticals said *"Umbralisib's approval offers MZL & FL patients a new treatment option and is a huge validation of Rhizen's drug discovery & development capabilities. This is a momentous occasion in Rhizen's journey as a successful biotech that speaks of the true ability of our team to discover & develop safe and effective therapies that can last the rigors of drug development. Further, we are keen to bring Umbralisib to Indian patients and we plan to initiate activities towards registration and approval there soon."*

Pranav Amin, Chairman, Rhizen Pharmaceuticals & Managing Director of Alembic Pharmaceuticals Ltd said *"We are extremely proud of this historic milestone for Rhizen, and of the fact that Umbralisib is the first NCE discovered by Indian scientists to secure a US FDA approval. We are committed to working together with TG Therapeutics and Rhizen Pharma to ensure uninterrupted supply of UKONIQ™. Umbralisib is the first discovery asset to come out of Rhizen's R&D efforts and this approval heralds the promise of the rest of Rhizen's deep pipeline and continuing efforts."*

About Umbralisib:

Umbralisib is the first and only oral inhibitor of phosphoinositide 3 kinase (PI3K) delta and casein kinase 1 (CK1) epsilon. PI3K-delta is known to play an important role in supporting cell proliferation and survival, cell differentiation, intercellular trafficking and immunity and is expressed in both normal and malignant B-cells. CK1-epsilon is a regulator of oncoprotein translation and has been implicated in the pathogenesis of cancer cells, including lymphoid malignancies. Umbralisib is indicated for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen and for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy. These indications are approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. More information on Umbralisib or UKONIQ™ can be found at https://www.tgtherapeutics.com/prescribing-information/uspi-ukon.pdf

About Alembic Pharmaceuticals Ltd:

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 products that are 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: APLL TD) (BSE: 533573)

About Rhizen Pharmaceuticals A.G.:

Rhizen Pharmaceuticals is an innovative, clinical-stage biopharmaceutical company focused on the discovery and development of novel onco-therapeutics. Since its establishment in 2008, Rhizen has created a diverse pipeline of proprietary drug candidates targeting several cancers and immune associated cellular pathways. Rhizen is headquartered in Basel, Switzerland. For additional information, please visit www.rhizen.com

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