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Alembic Pharma to bring novel lymphoma drug for Indian cancer patients

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Rhizen Pharmaceuticals, a clinical-stage oncology-focused biopharmaceutical company based in Switzerland, has announced that its novel next-generation PI3K-delta inhibitor, Umbralisib, which was licensed to TG Therapeutics, 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 Phase 2 UNITY-NHL Trial (NCT02793583); in MZL, an ORR of 49 per cent with 16 per cent complete responses and in FL an ORR of 43 per cent with 3 per cent complete responses were achieved, respectively.

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Umbralisib is a novel, next-generation, oral, once-daily, inhibitor of phosphoinositide 3 kinase (PI3K) delta and casein kinase 1 (CK1) epsilon and was discovered by Rhizen Pharma and subsequently licensed to TG Therapeutics at an IND stage (TGR 1202) in 2012.

Swaroop Vakkalanka, President & CEO, 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. 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, Alembic Pharmaceuticals Ltd said, “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.”