Rhizen Pharmaceuticals S.A. receives FDA Fast Track Designation for Tenalisib (RP6530), a highly selective dual PI3K delta/gamma inhibitor for the treatment of patients with relapsed and/or refractory Cutaneous T-cell Lymphoma (CTCL)

La Chaux-de-Fonds, Switzerland, Apr. 13, 2018 (GLOBE NEWSWIRE) -- Rhizen Pharmaceuticals S.A., today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for Tenalisib (RP6530), the Company's highly selective and orally active dual PI3K delta/gamma inhibitor, for the treatment of patients with relapsed and/or refractory Cutaneous T-cell Lymphoma (CTCL).

"We are pleased that Tenalisib (RP6530) has been granted Fast Track Designation, demonstrating the FDA's commitment to facilitate the development and expedite the review of our highly selective and orally active dual PI3K delta/gamma inhibitor as an important therapy for patients with relapsed and/or refractory Cutaneous T-cell Lymphoma (R/R CTCL)," said Swaroop Vakkalanka, Ph.D., Founder & President of Rhizen Pharmaceuticals S.A.

About FDA Fast Track Designation:

Fast Track Designation is awarded to drugs that treat a serious condition and fill an unmet medical need. Fast Track Designation enables the recipient to have more frequent interaction with and support from FDA, both through meetings and written communications, and also makes the drug eligible for Accelerated Approval and Priority Review. Accelerated Approval enables the use of surrogate and intermediate clinical endpoints, which can make the clinical trials process more efficient, and Priority Review reduces the stipulated time of FDA review of a new drug application (NDA) from 10 months to 6 months.

About Tenalisib (RP6530):

Tenalisib (RP6530) is a highly selective and orally active dual PI3K delta/gamma inhibitor with efficient translation of activity through enzyme, cell, and whole blood-based studies. Besides inhibiting growth of immortalized cancerous cell lines and primary patient leukemic/lymphoma cells, RP6530 plays a significant role in modulation of tumor microenvironment at clinically achievable concentrations. In preclinical studies, RP6530 reprograms macrophages from an immunosuppressive M2-like phenotype (pro-tumor) to an inflammatory M1-like state (anti-tumor), which can potentially enhance the activity of checkpoint inhibitors or overcome

resistance to these drugs. Tenalisib obtained US FDA Fast Track Designations for treatment of relapsed/refractory peripheral T-cell lymphoma and relapsed and/or refractory cutaneous T-cell lymphoma (R/R PTCL and R/R CTCL) in addition to Orphan-Drug Designations for treatment of peripheral and cutaneous T-cell lymphoma (PTCL and CTCL).

About Rhizen Pharmaceuticals S.A.:

Rhizen Pharmaceuticals is an innovative, clinical-stage biopharmaceutical company focused on the discovery and development of novel therapeutics for the treatment of cancer, immune and metabolic disorders. 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 La-Chaux-de-Fonds, Switzerland. For additional information, please visit Rhizen's website, www.rhizen.com.

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