Rhizen Pharmaceuticals S.A. receives FDA orphan-drug designation for Tenalisib (RP6530) for treatment of cutaneous T-cell lymphoma (CTCL)

La Chaux-de-Fonds, Switzerland, Apr. 9, 2018 (GLOBE NEWSWIRE) -- Rhizen Pharmaceuticals S.A., today announced that the U.S. Food and Drug Administration (FDA) has granted orphan-drug designation for the active moiety of Tenalisib (RP6530), the Company's highly selective and orally active dual PI3K delta/gamma inhibitor, for treatment of cutaneous T-cell lymphoma (CTCL).

"We are pleased to receive US FDA orphan-drug designations for the active moiety of Tenalisib (RP6530) for the treatment of peripheral and cutaneous T-cell Lymphoma (PTCL and CTCL), and we look forward to advancing the drug into further development for treatment of T-cell lymphoma," said Swaroop Vakkalanka, Ph.D., Founder & President of Rhizen Pharmaceuticals S.A.

About FDA Orphan-Drug Designation:

Orphan-Drug Designation is granted to a drug or biological product intended to treat a rare disease in the United States. A number of incentives are provided for an orphan-drug such as 7-year marketing exclusivity, tax credits for clinical development costs, exemption/waiver of application (filing) fees and assistance from the FDA Office of Orphan Products Development (OOPD) during the development process.

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 Designation for treatment of peripheral T-cell lymphoma (PTCL) 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.

Contact:
Kumar V. Penmetsa, Ph.D.
Executive Vice President, Corporate Development
Rhizen Pharmaceuticals S.A.
Telephone: +1-267-207-5707
Email: kvp@rhizen.com