Remix Therapeutics Granted FDA Fast Track Designation for REM-422 for the Treatment of Recurrent, Metastatic or Unresectable Adenoid Cystic Carcinoma

March 19, 2026

Preliminary Phase 1 Study Results Show Strong Anti-Tumor Activity and Favorable Safety Profile for First-in-Class Small Molecule MYB mRNA Degrader

No Approved Treatment Options for Patients with MYB-Driven Solid Tumor Adenoid Cystic Carcinoma

WATERTOWN, Mass., March 19, 2026 – Remix Therapeutics (Remix), a clinical-stage biotechnology company developing small molecule therapies to modulate RNA processing and address the underlying drivers of disease, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to first-in-class small molecule MYB mRNA degrader, REM-422, for the treatment of patients with recurrent, metastatic or unresectable adenoid cystic carcinoma (ACC) whose tumors express MYB transcripts containing a poison exon.

"Receiving Fast Track designation for REM-422 underscores the urgent need for new treatment options for patients with ACC," said Peter Smith, PhD, Co-Founder and Chief Executive Officer of Remix Therapeutics. "REM-422 represents a novel approach designed to target MYB, a key oncogenic driver in ACC that has historically been difficult to drug. This designation supports our ongoing efforts to expeditiously advance REM-422 through clinical development to bring this potential therapy to patients as quickly as possible."

REM-422 is a first-in-class, oral small molecule MYB mRNA degrader designed to reduce MYB expression by inducing incorporation of a poison exon in the MYB transcript, leading to degradation of the mRNA and suppression of MYB protein expression. MYB dysregulation is a hallmark driver of ACC and several hematologic malignancies. REM-422 is currently being investigated in the ongoing Phase 1/2 **ARIA** (**A** study of **R**EM-422 **I**n **A**denoid cystic carcinoma) study, evaluating safety, pharmacokinetics and preliminary anti-tumor activity in patients with recurrent or metastatic, and unresectable ACC.

The FDA's Fast Track program is designed to accelerate the development and review of drugs that treat serious conditions and address unmet medical needs. The designation for REM-422 was based on positive preliminary results from a Phase 1 clinical trial evaluating REM-422 in patients with recurrent or metastatic ACC. REM-422 is the first oral mRNA degrader of MYB demonstrating proof-of-mechanism and proof-of-concept in ACC along with a favorable safety profile. Anti-tumor activity was observed in patients with recurrent, metastatic or unresectable ACC whose tumors express MYB transcripts containing a poison exon.

About REM-422

REM-422 is a first-in-class, potent, selective, and oral small molecule mRNA degrader that induces the reduction of MYB mRNA and subsequent protein expression. REM-422 functions by facilitating the incorporation of a poison exon in the MYB mRNA transcript, leading to nonsense-mediated decay of the transcript. REM-422 is currently in Phase 1/2 clinical studies in both Adenoid Cystic Carcinoma (ACC) and Acute Myeloid Leukemia (AML) or high-risk myelodysplastic syndrome (HR-MDS). The U.S. Food and Drug Administration granted REM-422 Orphan Drug Designation for ACC and AML and Fast Track designation for ACC.

About the ARIA (A study of REM-422 In Adenoid cystic carcinoma) Clinical Trial

This Phase 1/2, open-label, non-randomized, multicenter study (NCT06118086) is investigating REM-422 in patients with recurrent, metastatic or unresectable Adenoid Cystic Carcinoma (ACC). The study includes a Dose Escalation Phase and a Dose Expansion Phase. The purpose of the Dose Escalation Phase is to determine the maximum tolerated dose and/or recommended Phase 2 dose (RP2D) of REM-422 in patients with recurrent, metastatic, or unresectable ACC. The purpose of Dose Expansion is to further evaluate the safety and anti-tumor activity of the REM-422 RP2D in biomarker positive patients.

About Adenoid Cystic Carcinoma

Adenoid cystic carcinoma (ACC) is a solid tumor that most commonly arises in the salivary glands characterized by frequent recurrent, perineural invasion and dysregulation of the MYB oncogene. Depending on the location of the tumor, symptoms may include numbness of the face, difficulties swallowing, changes in vision, or difficulty breathing, among others. Many therapeutic approaches, such as chemotherapy, kinase inhibitors, and immunotherapy have been studied in ACC with modest or disappointing results, and there remain no approved treatment options.

About Remix Therapeutics

Remix Therapeutics is a clinical-stage biotechnology company developing novel small molecule therapies designed to reprogram RNA processing and address disease drivers at their origin. Remix's REMaster™ technology platform leverages cutting-edge data science, biomolecular sciences and chemistry approaches to identify orally administered compounds that modulate gene expression. Remix's innovative therapeutic approach led to the discovery of REM-422, a first-in-class RNA processing modulator in oncology, now being evaluated in Phase 1/2 clinical studies to treat acute myeloid leukemia (AML), high-risk myelodysplastic syndrome (HR-MDS) and adenoid cystic carcinoma (ACC). For more information visit www.remixtx.com.