# Kestrel Therapeutics Receives FDA Fast Track Designation for KST-6051, a Potential Best-in-Class Pan-KRAS Inhibitor, in the treatment of KRAS-Mutant Advanced Solid Tumors

Watertown, MA., September 15, 2026 – Kestrel Therapeutics Inc. (“Kestrel” or the “Company”), a clinical-stage biotechnology company developing next-generation small-molecule inhibitors targeting mutant KRAS, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to KST-6051, a potential best-in-class, oral pan-KRAS inhibitor, for the treatment of patients with advanced or metastatic solid tumors harboring KRAS mutations.

Fast Track is a designation created to facilitate the development and expedite the review of drugs intended to treat serious conditions and address an unmet medical need. Companies that receive Fast Track designation benefit from more frequent communication with the FDA throughout development, and may be eligible for Accelerated Approval, Priority Review, and rolling review of a New Drug Application (NDA), provided relevant criteria are met.

"FDA Fast Track designation for KST-6051 is an important regulatory milestone for Kestrel, based on the strength of our preclinical data package. This designation will allow us to work more closely with the FDA as we advance KST-6051 through our ongoing Phase 1 study, with the goal of bringing a much-needed treatment option to patients with KRAS-mutant tumors as efficiently as possible," said Frank Haluska, MD, PhD, President and Chief Executive Officer of Kestrel Therapeutics.

KST-6051 is being evaluated in an ongoing first-in-human (FIH), dose-escalation Phase 1 study, denoted FALCON (NCT07458347) in patients with advanced or metastatic KRAS-mutant solid tumors.

**About Fast Track Designation**

The FDA's Fast Track program is designed to facilitate development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to patients earlier. Fast Track addresses a broad range of serious conditions, and a drug that receives Fast Track designation is eligible for more frequent meetings and written communication with the FDA, as well as the possibility of Priority Review and rolling submission of a marketing application.

**About KST-6051**

KST-6051 is a potential best-in-class, oral pan-KRAS inhibitor, developed for the treatment of KRAS-driven cancers. KST-6051 is a potent and selective inhibitor of KRAS with activity against KRAS in both its active (GTP-bound) and inactive (GDP-bound) states. Preclinical data demonstrate robust on-target pathway modulation, anti-proliferative activity, and efficacy at well-tolerated doses in multiple human *KRAS* mutant tumor models. The Company is initiating a Phase 1 study in patients with *KRAS*-mutant advanced/metastatic solid tumors. Its clinical development will ultimately address pancreatic ductal adenocarcinoma (PDAC), colorectal cancer (CRC), non-small cell lung cancer (NSCLC), and other KRAS-driven malignancies.

**About Kestrel Therapeutics, Inc.**

Kestrel Therapeutics is a privately held clinical-stage biotechnology company pioneering small-molecule therapies that directly address oncogenic drivers of cancer, focusing on next-generation inhibitors of

mutated KRAS proteins. *KRAS* is estimated to be mutated in approximately 30% of all malignancies. The Company's lead candidate, KST-6051 offers the potential to treat a broad spectrum of KRAS-driven solid tumors, an area of significant unmet patient need. Based in Watertown, MA, Kestrel is backed by leading life-science investors including Pfizer Ventures and Santé Ventures, and has entered into a strategic agreement that grants AbbVie an exclusive option to acquire the Company based on defined development milestones. Kestrel is led by a team with deep expertise and a record of success in oncology drug discovery and development.

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