Accent Therapeutics Announces FDA Clearance of IND Application for ATX-559, a First-In-Class Oral DHX9 Inhibitor

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Enables ATX-559 Phase 1 study in solid tumor patients with a focus on BRCA1/2-deficient breast cancer and solid tumors with microsatellite instability (MSI-H) and/or deficient mismatch repair (dMMR); first patient dosed anticipated in Q4 2024

Second program targeting KIF18A on track to enter clinical trials in early 2025, underscoring rapid advancement of novel therapies

Clinical Advisory Board (CAB) of global oncology drug development experts formed to support the advancement of Accent's clinical pipeline

LEXINGTON, Mass., Oct 24, 2024– Accent Therapeutics, a biopharmaceutical company pioneering novel small molecule targeted cancer therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for ATX-559, a first-in-class DHX9 inhibitor. In addition, Accent has established a Clinical Advisory Board (CAB) to help guide the Company's progress in the clinic.

The ATX-559 Phase 1/2 trial (NCT06625515) is expected to begin dosing patients with a focus on BRCA1- or BRCA2-deficient breast cancer and patients with MSI-H and/or dMMR solid tumors (including certain patients with colorectal, endometrial, gastric, and other cancers) in the fourth quarter of 2024. The clinical study will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of ATX-559. For more information on the trial, visit the study page on ClinicalTrials.gov.

"The FDA's IND clearance is a pivotal moment for Accent Therapeutics, propelling our lead program into the clinical arena. This milestone not only validates our scientifically rigorous approach to identifying innovative targets, but also brings us one step closer to helping cancer patients with significant unmet need," said Jason Sager, M.D., Chief Medical Officer of Accent Therapeutics. "ATX-559 has shown remarkable promise in preclinical studies, and we're excited to now evaluate its potential to meaningfully improve outcomes for patients facing these challenging malignancies."

As Accent prepares to initiate its first clinical trial, the company has also established a Clinical Advisory Board to guide the advancement of its clinical pipeline. The Clinical Advisory Board consists of renowned clinician-scientists and leaders whose strategic insights and clinical expertise will support the Company's efforts to advance its mission of creating life-changing therapeutics for patients living with cancer.

The newly formed Clinical Advisory Board includes:

- **Lillian L. Siu, M.D., FRCPC**, medical oncologist, Director of the Phase I Program at Princess Margaret Cancer Centre, Professor of Medicine at the University of Toronto, and President-Elect of the American Association for Cancer Research (AACR)
- **Josep Tabernero, M.D., Ph.D.**, Professor of Medicine, Head of the Medical Oncology Department at the Vall d'Hebron Barcelona Hospital Campus, and Director of the Vall d'Hebron Institute of Oncology (VHIO)
- **Sam Blackman, M.D., Ph.D.**, co-founder and Head of Research and Development of Day One Biopharmaceuticals

"We are honored to have such distinguished experts join our Clinical Advisory Board as we advance our programs into the clinic," said Shakti Narayan, Ph.D., J.D., Chief Executive Officer of Accent Therapeutics. "Their experience will be invaluable as we work to bring transformative therapies to patients."

Accent is also on track to advance its second program, targeting KIF18A in chromosomally instable tumors, into the clinic with a Phase 1 trial anticipated to begin in early 2025. This marks an exciting phase of growth for the company as it continues to build on its foundational platform technology to develop innovative cancer therapies.

About ATX-559

ATX-559 is a first-in-class DHX9 inhibitor with the potential to address high unmet need indications not adequately served by existing therapies, such as BRCA-deficient tumors (including breast, ovarian, and others), MSI-H and/or dMMR cancers (including colorectal, endometrial, gastric, and others) and additional undisclosed cancer types representing large patient populations. DHX9 is a DNA/RNA helicase that has been reported to play important roles in replication, transcription, translation, RNA splicing, RNA processing, and maintenance of genomic stability. Inhibition of DHX9 exploits key tumor vulnerabilities, resulting in cancer-specific cell death, and thus this enzyme represents a compelling novel oncology target. Accent retains full worldwide rights to ATX-559 and the DHX9 program.

About KIF18A

Accent's second lead program is a potential best-in-class inhibitor for KIF18A which may address a large patient population across several cancer indications, including ovarian and triple negative breast cancer (TNBC). KIF18A is a mitotic kinesin motor protein critical for cell division in select tumors with chromosomal instability. A subset of tumor cells with an abnormal number of chromosomes (aneuploid) are reliant on KIF18A and show rapid cell killing in vitro and in vivo upon KIF18A inhibitor treatment, while cells with normal numbers of chromosomes (euploid) are unaffected.

About Accent Therapeutics

Accent Therapeutics is pioneering a new class of small molecule precision cancer therapies targeting critical intracellular dependencies that span multiple types of cancer. Building upon industry-leading expertise in RNA-modifying proteins (RMPs) and the systematic mapping of both the RMP space and adjacent high-value areas for drug discovery, the company is building a flexible model that allows for

a diversity of approaches to developing potentially transformative biomarker-driven cancer medicines. Accent's therapies are designed for both novel and known, but suboptimally addressed, high-impact oncology targets with the potential to benefit large patient populations with significant unmet need. For more information on Accent's mission to translate extraordinary science into life-changing therapeutics for patients living with cancer, visit www.accenttx.com or follow us on LinkedIn.

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