HAYA Therapeutics Announces First Cohort Dosed in Phase 1 Clinical Trial of HTX-001, an Investigational Precision Cellular Reprogramming Therapy for Cardiac Fibrosis

HTX-001 is a first-in-class antisense oligonucleotide designed to downregulate WISPER lncRNA, a driver of fibrosis in the heart

Phase 1a/b trial to evaluate the safety and tolerability of HTX-001 in healthy volunteers, followed by patients with nonobstructive hypertrophic cardiomyopathy (nHCM)

LAUSANNE, Switzerland and SAN DIEGO, USA - (May 20, 2026) - HAYA Therapeutics SA, a clinical-stage biotechnology company pioneering precision RNA-guided therapeutics that target the regulatory genome to reprogram disease-driving cell states in common, chronic, and age-related diseases, announced that the first cohort has been fully enrolled and dosed in the company's Phase 1 clinical trial evaluating HTX-001, its first-in-class long non-coding RNA (lncRNA)-targeting therapy for nonobstructive hypertrophic cardiomyopathy (nHCM).

HTX-001 offers a differentiated and potentially disease-modifying approach to treating patients with nHCM. The investigational molecule is an antisense oligonucleotide designed to downregulate *WISPER*, a heart stress-specific lncRNA overexpressed in patients with hypertrophic cardiomyopathy, including nHCM. By decreasing *WISPER* expression in cardiac myofibroblast cells, HTX-001 is intended to promote cell-state reprogramming of this fibrotic and pathological cell population back toward a healthy state. Preclinical studies demonstrate that HTX-001 reduces pathological cardiac fibrosis and improves heart function.

The advancement of HTX-001 into the clinic represents a significant milestone in translating HAYA's foundational regulatory genome science into a potentially new therapeutic approach. *WISPER* was first discovered in 2017 by Samir Ounzain, Ph.D., co-founder and CEO of HAYA Therapeutics, who identified its role in cardiac fibrosis and remodeling. Building on this discovery, Dr. Ounzain co-founded HAYA with Daniel Blessing, Ph.D., co-founder and CSO, who has led the research and development team responsible for advancing the tailored design and translation of HTX-001 from scientific concept into clinical development.

"For patients diagnosed with nHCM, this clinical study marks a major milestone," said Jordan Shin, M.D., Ph.D., CMO of HAYA Therapeutics. "A targeted anti-fibrotic therapy for nHCM offers

the potential to address an important unmet medical need as currently available treatments fail to address the underlying fibrotic process that drives disease."

nHCM accounts for an estimated 30-60% of all hypertrophic cardiomyopathy cases. The condition is characterized by increased wall thickness in the heart, hypertrophy in the left ventricular cavity, impaired diastolic function and marked fibrosis. While significant progress has been made in understanding the cellular biology underlying nHCM, currently available therapeutic approaches do not directly address the fibrotic pathology or diastolic dysfunction that drive the disease.

"Our approach is built on our belief that the regulatory genome holds the instructions that drive diseased cell states. With HTX-001, we are translating that biology into an investigational precision RNA-guided therapy that is designed to enable the reprogramming of cardiac fibroblasts, the sentinel effector cells of cardiac fibrosis and pathological remodeling of the myocardium. For patients living with nHCM, where fibrosis remains a driver of disease and current options are limited, our goal is to bring forward a tractable, causal therapeutic approach for an area of significant unmet need," said Dr. Ounzain.

"This is a meaningful milestone for the entire HAYA team as we advance our science from the laboratory into clinical development," added Dr. Blessing. "Dosing of the first cohort reflects the significant progress we have made in translating our RNA-guided regulatory genome platform into an investigational first-in-class therapeutic candidate for patients."

The Phase 1a/b study of HTX-001 will evaluate safety, tolerability, pharmacokinetics and pharmacodynamics in healthy volunteers and nHCM patients across multiple-ascending dose cohorts.

HTX-001 is an investigational therapy candidate and has not been approved by the U.S. Food and Drug Administration, the European Medicines Agency, or any other regulatory authority. Its safety and ability to translate into clinical benefit remain to be established.

About HAYA Therapeutics

HAYA Therapeutics is a clinical-stage precision medicine company developing programmable, first-in-class RNA-guided therapeutics that target the regulatory genome to reprogram disease-driving cell states. HAYA's innovative platform decodes the causal biology of pathological cell states and the long non-coding RNAs (lncRNAs) that regulate them, translating these insights into tractable therapeutic candidates designed to address disease at its source and restore cellular health. HAYA is advancing a broad pipeline of RNA-guided medicines for fibrosis-driven and chronic, age-related diseases.

HAYA's lead investigational candidate, HTX-001, is an antisense oligonucleotide targeting *WISPER*, and is currently being evaluated in a Phase 1 clinical trial, initially for nonobstructive hypertrophic cardiomyopathy (nHCM).

HAYA is headquartered at the life sciences park Biopôle in Lausanne, Switzerland, with laboratory facilities at Lilly Gateway Labs in San Diego, California. For more information, please visit www.hayatx.com and follow HAYA on X and LinkedIn.

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