Released July 21, 2020 7:00 AM ET via PR Newswire

Elevation Oncology Emerges from Stealth with $32.5M Series A to Develop Precision Medicines for Tumors Harboring Rare Genetic Driver Alterations

- $32.5M Series A Financing Led by Aisling Capital, Vertex Ventures HC, Qiming Venture Partners USA, Driehaus Capital Management, and BVF Partners -

- Registration-Enabling Phase 2 CRESTONE Study Now Enrolling Patients with Solid Tumors of Any Origin that have an NRG1 Gene Fusion -

- CRESTONE Enrollment Enhanced Through Strategic Partnerships with Next Generation Sequencing Diagnostic Providers Including Ashion Analytics, Strata Oncology, and Tempus to Advance Patient Enrollment Practices for Genomically-driven, Tumor-agnostic Clinical Trials –

NEW YORK, NY – July 21, 2020 – Elevation Oncology, a clinical stage biopharmaceutical company focused on the development of precision medicines for patients with genomically defined cancers, announced today the launch of the Company with a $32.5M Series A financing, initiation of the Phase 2 CRESTONE study, and new partnerships with Next Generation Sequencing diagnostic providers including Ashion Analytics, Strata Oncology, and Tempus to explore innovative models for real-time identification, patient referral, and enrollment of patients with tumors driven by rare genomic alterations. The Series A financing was led by Aisling Capital and a syndicate of investors including Vertex Ventures HC, Qiming Venture Partners USA, Driehaus Capital Management, and BVF Partners.

"At Elevation Oncology, we envision a future in which each unique genomic testing result can be matched with a purpose-built precision medicine and bring clarity to the patient treatment journey. Focused drug development paired with open collaboration will be instrumental for our industry to fully realize the potential of precision medicine for all patients with cancer," said Shawn Leland, PharmD, RPh, Founder and Chief Business Officer of Elevation Oncology. "With our lead development program, seribantumab, and the partnerships announced today, we are taking our first steps toward this future."

Seribantumab and the Tumor-agnostic CRESTONE Study

Seribantumab is a fully human IgG2 monoclonal antibody that binds to human epidermal growth factor receptor 3 (ERBB3 or HER3). HER3 is traditionally activated through binding of its primary ligand, neuregulin-1 (NRG1). The NRG1 gene fusion is a rare genomic alteration that combines NRG1 with another partner gene to create chimeric NRG1 "fusion proteins."

Seribantumab was acquired in 2019 by Elevation Oncology, and the development program builds on prior clinical experience from over 800 patients demonstrating consistent safety and tolerability. Previous clinical trials with seribantumab did not select for tumors with an NRG1 fusion. The CRESTONE study leverages seribantumab's rational design with recent discoveries on the significance of the NRG1 gene fusion and improvements in diagnostic sensitivity. Novel preclinical data generated by Elevation Oncology demonstrating the ability of seribantumab to prevent the activation of HER3 signaling in NRG1 fusion models are supportive of CRESTONE and are expected to be released in publications and at scientific conferences later this year.

Although rare, NRG1 gene fusions are oncogenic drivers that can be found in a variety of solid tumors, including lung, pancreatic, gallbladder, breast, ovarian, colorectal, and neuroendocrine cancers, and sarcomas. Importantly, NRG1 gene fusions are mutually exclusive with other known driver mutations and are considered a unique oncogenic driver event essential for tumor cell survival. Following recent regulatory approvals of tumor-agnostic treatments associated with oncogenic drivers, CRESTONE is designed as a registration-enabling Phase 2 "basket trial" to evaluate the efficacy and safety of seribantumab in patients with any solid tumor that harbor an NRG1 fusion.

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"Genomic testing and matched precision therapeutics are creating a revolution in oncology development and regulatory approval paths," said Lori Kunkel, MD, Chair of the Elevation Oncology Scientific Advisory Board and former Chief Medical Officer LOXO Oncology. "The FDA has recently approved several oncology therapeutics for tumor-agnostic indications. I am encouraged to see the evolution in our understanding of how to achieve better clinical outcomes to address the unmet clinical need among patients with a genomically defined cancer, regardless of its tissue of origin. The CRESTONE study potentially expands the actionability of genomic tests to tumors with an NRG1 fusion and is a promising approach for furthering this genomically-driven tumor-agnostic development pathway."

Innovative Models for Patient Enrollment

Sarah Cannon Research Institute (Sarah Cannon) has been selected as the first strategic site for CRESTONE and is open and enrolling patients today. Sarah Cannon's world class clinical research leadership and insights as well as additional prospectively selected clinical sites are foundational to ensuring rigorous study conduct.

"Identifying potential driver alterations, such as NRG1 gene fusions, enables us to approach cancer treatment in a more targeted way," said David Spigel, MD, Chief Scientific Officer, Sarah Cannon Research Institute at Tennessee Oncology and one of the investigators of the CRESTONE study. "Today, all cancer patients facing a treatment decision without clear standard of care should consider comprehensive genomic testing for their tumor. Collaborations across the healthcare ecosystem help to ensure that the value of each genomic test is maximized and to expand access to critical treatment opportunities for patients."

Diagnostic partnerships will enhance traditional patient enrollment in the CRESTONE study through real-time, nationwide identification of NRG1 fusion positive patients within the Ashion, Strata Oncology, Tempus, and other partner networks. Through various partnership models, patients may also be enrolled in CRESTONE through active referral to current strategic sites or "just-in-time" site initiation.

These innovative models address specific challenges encountered by genomically-driven, tumor-agnostic trials such as the rarity of genomic driver alterations and the impracticality of comprehensive clinical site coverage by both geography and organ-system of study. In addition, these models may reduce the burden on patients by minimizing the number of diagnostic tests they may need and maximizing the treatment opportunities available to them, regardless of where they may live. Bringing clinical trials to patients using the "just-in-time" site initiation model can further help to minimize travel and keep patients safe in the face of ongoing travel restrictions due to COVID-19.

"With the strong backing of a dynamic and experienced investor syndicate, Elevation Oncology is well positioned to execute on our mission of delivering precision medicines to physicians and their patients with cancer," said Steve Elms, Chairman and Interim Chief Executive Officer of Elevation Oncology and Managing Partner of Aisling Capital. "Our development approach to seribantumab sets the stage for our broader vision: the elevation of precision medicine to the forefront of every patient journey through building a collaborative industry-wide ecosystem. Together with diagnostic developers, clinical researchers, patient advocates, and the Elevation Oncology team, we are looking to build a pipeline of precision oncology medicines that can amplify each other's efforts towards our shared goal of improving patient outcomes."

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About Elevation Oncology
Elevation Oncology is founded on the belief that every patient with cancer deserves to know what is driving the growth of their disease and have access to therapeutics that can stop it. We make genomic tests actionable by selectively developing drugs to inhibit the specific alterations that have been identified as drivers of disease. Together with our peers we work towards a future in which each unique test result can be matched with a purpose-built precision medicine to enable an individualized treatment plan for each patient. Our lead candidate, seribantumab, inhibits tumor growth driven by NRG1 fusions and is currently being clinically tested in the Phase 2 CRESTONE study for patients with tumors of any origin that have an NRG1 fusion. Details on CRESTONE are available at www.NRG1fusion.com. For more information visit www.ElevationOncology.com.

About Ashion Analytics
Ashion Analytics, LLC, is a CLIA-certified and CAP-accredited clinical laboratory that uses advanced genomic technologies to offer a wide range of testing capabilities to assist physicians, health systems, research and commercial partners to provide precision cancer treatments. Ashion was developed and launched by the Translational Genomics Research Institute (TGen), an affiliate of City of Hope. TGen is a pioneer in the use of genomics to identify treatment options for cancer patients.

About Strata Oncology
Strata Oncology, Inc. is a precision medicine company dedicated to transforming cancer care by building a platform to systematize precision oncology across a network of health systems and biopharma companies. Strata Oncology empowers health systems to deliver a comprehensive, system-wide precision oncology program that integrates cutting-edge tumor molecular profiling and a portfolio of biomarker-guided with routine care, so that all patients with advanced cancer have the opportunity to benefit. This large network of trial-ready health systems provides a mechanism to rapidly and predictably enroll precision therapy trials. For more information visit www.strataoncology.com.

About Tempus
Tempus is a technology company advancing precision medicine through the practical application of artificial intelligence in healthcare. With one of the world's largest libraries of clinical and molecular data, and an operating system to make that data accessible and useful, Tempus enables physicians to make real-time, data-driven decisions to deliver personalized patient care and in parallel facilitates discovery, development and delivery of optimal therapeutics. Additionally, the TIME Trial™ Network leverages a unique and comprehensive infrastructure to bring the right clinical trials to the right patients in under two weeks. The goal is for each patient to benefit from the treatment of others who came before by providing physicians with tools that learn as the company gathers more data. For more information, visit tempus.com.

Media Contact:
Elevation Oncology
David Rosen, Argot Partners
Phone: +1 (716) 371-1125
Email: media@ElevationOncology.com