Castle Creek Biosciences Acquires Novavita Thera to Expand Innovative Cell and Gene Therapy Platform

- Company adds in vivo capabilities to existing ex vivo approach for development of novel gene therapies -

- Company broadens development pipeline to address rare liver diseases, including hereditary tyrosinemia type 1 (HT1) -

- Joseph Lillegard, MD, PhD, and Robert A. Kaiser, PhD, DABT, join the Castle Creek leadership team -

EXTON, PA, January 10, 2022 — Castle Creek Biosciences, Inc., a late-clinical stage cell and gene therapy company focused on developing and preparing to commercialize disease-modifying and potentially curative therapies for rare genetic diseases, today announced it has acquired Novavita Thera, Inc., a preclinical gene therapy company focused on rare liver and metabolic diseases. The acquisition expands Castle Creek's technology platform by adding in vivo capabilities to its existing ex vivo approach, and broadens Castle Creek's development pipeline beyond skin and connective tissue disorders to rare liver diseases.

"This acquisition is a significant inflection point for Castle Creek and positions us to expand our research and development efforts using a versatile, dual technology platform that will accelerate the discovery of disease-modifying and potentially curative therapies for people living with rare diseases," said Matthew Gantz, president and chief executive officer of Castle Creek Biosciences. "The ability to leverage both ex vivo and in vivo based approaches is a distinct advantage that few cell and gene therapy companies can offer. We are now in position to pursue new indications for devastating rare diseases, while also advancing our ongoing pivotal clinical trial in recessive dystrophic epidermolysis bullosa (RDEB)."

With the acquisition of Novavita Thera, formerly a Cytotheryx, Inc., company, Castle Creek will initially develop a gene therapy for hereditary tyrosinemia type 1 (HT1), a rare inborn error of metabolism caused by a lack of the enzyme fumarylacetoacetate hydrolase (FAH) which leads to accumulation of tyrosine and its metabolites in the liver. HT1 affects approximately 1:100,000 live births and leads to cirrhosis, liver failure, hepatocellular carcinoma, and is ultimately fatal if untreated. Liver transplantation is currently the only curative treatment available for HT1.

Castle Creek will advance the development of LV-FAH, a potential therapy based on a lentiviral vector containing a functional copy of the human FAH gene that is administered directly to the patient through the portal vein. The therapy is designed to transduce hepatocytes and deliver the FAH enzyme that is deficient in these cells. Castle Creek plans to submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for LV-FAH in HT1. Castle Creek also continues to progress several additional candidates targeting other rare liver and metabolic diseases and skin and connective tissue disorders.

In connection with the acquisition, Joseph Lillegard, MD, PhD, has joined Castle Creek as chief scientific officer. Dr. Lillegard is a board-certified pediatric and adult general, thoracic and fetal surgeon at the Children's Hospital of Minnesota, and led the cell and gene therapy research lab at

Mayo Clinic that discovered LV-FAH. Robert A. Kaiser, PhD, DABT, has also joined the company as vice president of preclinical development. Dr. Kaiser is a board-certified toxicologist with over a decade of experience designing, conducting, and reporting preclinical and IND-enabling studies. Dr. Lillegard and Dr. Kaiser will be the company leads for Castle Creek's recently announced research collaboration with Mayo Clinic to advance discovery and development of investigational gene therapy candidates for the treatment of osteogenesis imperfecta and classical Ehlers-Danlos syndrome.

"It is an exciting time to join Castle Creek, a company that has already established an impressive research and development program in cell and gene therapies with proven clinical development and in-house manufacturing capabilities," said Dr. Lillegard. "I look forward to collaborating with the company's dedicated team on development of novel gene therapies. We believe our work to evaluate the safety of in vivo lentiviral vector administration in HT1 has the potential to be a precedent setting approach that can be applied to a range of new therapeutic areas for underserved patient populations."

About Castle Creek Biosciences, Inc.

Castle Creek Biosciences, Inc. is a late-clinical stage cell and gene therapy company focused on developing and preparing to commercialize disease-modifying and potentially curative therapies for patients living with rare genetic diseases. Castle Creek's most advanced product candidate, dabocemagene autoficel (FCX-007, D-Fi), an ex vivo, autologous gene therapy, is currently being evaluated in a Phase 3 clinical trial for the localized treatment of chronic wounds due to recessive dystrophic epidermolysis bullosa (RDEB). The company is also evaluating FCX-013, an ex vivo, autologous gene therapy, in a Phase 1/2 clinical trial for the treatment of moderate to severe localized scleroderma. In addition, LV-FAH, an in vivo, investigational gene therapy candidate, is being assessed in preclinical studies for the treatment of hereditary tyrosinemia type 1 (HT1). Castle Creek is pursuing discovery and development of early-stage novel product candidates utilizing its dual platform of ex vivo and in vivo technologies to expand its robust pipeline. The company operates an in-house, commercial-scale manufacturing facility in Exton, Pennsylvania. Castle Creek Biosciences, Inc. is a portfolio company of Paragon Biosciences, LLC. For more information, visit https://castlecreekbio.com/ or follow Castle Creek on Twitter @CastleCreekBio.

About Paragon Biosciences, LLC

Paragon is a global life science leader that creates, builds and funds innovative biology-based companies in three key areas: cell and gene therapy, adaptive biology and advanced biotechnology. The company's current portfolio includes Castle Creek Biosciences, CiRC Biosciences, Emalex Biosciences, Evozyne, Harmony Biosciences, Qlarity Imaging, Skyline Biosciences, and a consistent flow of incubating companies created and supported by the Paragon Innovation Capital™ model. Paragon stands at the intersection of human need, life science, and company creation. For more information, please visit https://paragonbiosci.com/.

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