Castle Creek Biosciences Awarded FDA Orphan Products Development Grant to Support DeFi-RDEB, a Pivotal Phase 3 Study of FCX-007 Investigational Gene Therapy for Recessive Dystrophic Epidermolysis Bullosa

- RDEB is a devastating, rare genetic blistering disease with no FDA-approved treatments currently available -

Exton, PA, October 21, 2021 — Castle Creek Biosciences, Inc., a clinical-stage cell and gene therapy company focused on developing and commercializing disease-modifying therapies for patients suffering from rare diseases for which there is a lack of available treatment options, today announced that the U.S. Food & Drug Administration (FDA) Office of Orphan Products Development (OOPD) has awarded the company a $1.825 million research grant over four years (#1R01–FD007289-01). The grant supports a meaningful portion of the Phase 3 clinical development of dabocemagene autoficel (FCX-007, D-Fi), an investigational gene therapy for the treatment of recessive dystrophic epidermolysis bullosa (RDEB).

“We are honored to be awarded this highly competitive research grant for the ongoing clinical development of FCX-007, which has the potential to transform the lives of people suffering from dystrophic epidermolysis bullosa (DEB),” said Mary Spellman, M.D., Chief Medical Officer of Castle Creek Biosciences, and Principal Investigator for the grant. “We are committed to advancing our study of FCX-007 to develop a durable personalized therapy for the localized treatment of chronic wounds due to RDEB and will continue to work closely with the FDA as our program progresses.”

The Congressionally-funded Orphan Products Development Grants Program is designed to enhance the development of medical products for patients with rare diseases. RDEB is a progressive, devastatingly painful and debilitating, rare genetic disorder, and one of the most chronic and severe forms of DEB. RDEB causes painful blistering, wounds and scarring in response to trauma to the skin, including friction due to typical activities such as rubbing or scratching. There are currently no FDA-approved treatments available for the treatment of DEB.

The FDA has granted Orphan Drug designation to FCX-007 for the treatment of DEB. In addition, FCX-007 has been granted Rare Pediatric Disease, Fast Track, and Regenerative Medicine Advanced Therapy designations by the FDA for treatment of RDEB.

About FCX-007

Castle Creek Biosciences’ dabocemagene autoficel (FCX-007, D-Fi) is being developed to address the deficiency of functional type VII collagen protein (COL7) in patients with dystrophic epidermolysis bullosa (DEB). FCX-007 is comprised of autologously-derived dermal fibroblasts genetically modified with a lentiviral vector containing the *COL7A1* gene to express COL7. FCX-007 is locally administered by injection directly into the papillary dermis of persistent and non-healing recurrent wounds of DEB where the COL7 protein can support the formation of anchoring fibrils in the skin.

About the Phase 3 Study of FCX-007 (DeFi-RDEB)

DeFi-RDEB is a multi-center, within-patient randomized, controlled, open-label, Phase 3 clinical trial of FCX-007 designed to enroll approximately 24 people living with RDEB. Each participant's target wounds are paired and then randomized to receive FCX-007 or remain untreated. Up to three target wound pairs are identified for each participant. The primary outcome measure is complete wound closure of the first wound pair at week 24. Currently, there are five trial locations recruiting participants including Stanford University in Stanford, California; Children's Hospital Colorado in Aurora, Colorado; Dell Children's Medical Group in Austin, Texas; Solutions Through Advanced Research, Inc. in Jacksonville, Florida; and Mayo Clinic in Rochester, Minnesota. More information about the Phase 3 trial is available at ClinicalTrials.gov and by searching the identifier NCT04213261, and also at DeFi-RDEB.com.

About Castle Creek Biosciences, Inc.

Castle Creek Biosciences, Inc. is a clinical-stage cell and gene therapy company focused on developing and commercializing disease-modifying therapies for patients suffering from rare diseases for which there is a lack of available treatment options. The company's proprietary autologous fibroblast platform potentially allows for the development of personalized, targeted and redosable cell-based gene therapy product candidates for monogenic and chronic disorders. The company's most advanced product candidate, dabocemagene autoficel (FCX-007, D-Fi), 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 currently evaluating FCX-013 in a Phase 1/2 clinical trial for the treatment of moderate to severe localized scleroderma. In addition, Castle Creek Biosciences is pursuing discovery and potential development of early-stage novel product candidates with the goal of expanding its robust pipeline into other rare diseases and broader indications where there are significant unmet needs. The company operates an in-house, commercial-scale manufacturing facility in Exton, Pennsylvania that benefits from the validated systems and processes previously implemented at the site for manufacture of an FDA-approved cell therapy product. 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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