Castle Creek Biosciences Announces First Patient Dosed in DeFi-RDEB Phase 3 Clinical Trial of Debcoemagene Autoficel (D-Fi) Gene Therapy for Recessive Dystrophic Epidermolysis Bullosa

- Company manufacturing and distributing D-Fi at in-house, cGMP commercial-scale facility in greater Philadelphia area –

Exton, PA., October 28, 2020 — Castle Creek Biosciences, Inc, a privately-held, clinical-stage cell and gene therapy company leveraging its proprietary fibroblast technology platform to develop and commercialize innovative personalized therapies for underserved disorders with high unmet medical needs, today announced the first patient has been dosed in the DeFi-RDEB Phase 3 clinical trial evaluating debcoemagene autoficel (D-Fi), the company's lead gene therapy candidate formerly designated FCX-007, in recessive dystrophic epidermolysis bullosa (RDEB).

"Our late-stage Phase 3 trial of D-Fi continues to progress for the localized treatment of RDEB, a devastating condition for too many families who currently do not have options beyond palliative care," said John Maslowski, Chief Executive Officer of Castle Creek Biosciences. "Dosing the first patient in the DeFi-RDEB study is a critical milestone that brings us closer to offering relief for the chronic, painful and debilitating wounds of RDEB that patients endure every day."

RDEB is a severe and debilitating form of epidermolysis bullosa that causes blistering, open wounds and scarring in response to friction, including normal daily activities like rubbing or scratching. Castle Creek Biosciences is using its proprietary fibroblast technology platform to develop and evaluate D-Fi for localized treatment of wounds that can lead to serious health complications in RDEB patients. D-Fi is designed to deliver functional type VII collagen protein (COL7) intradermally at the site of wounds in an outpatient setting in two or more treatment sessions, 12 weeks apart. The company is manufacturing D-Fi at its in-house, current good manufacturing practices (cGMP), commercial-scale facility located in Exton, Pennsylvania.

"Our goal is to develop a durable personalized treatment that is compatible with each patient's unique biology," said Mary Spellman, M.D., Chief Medical Officer of Castle Creek Biosciences. "We have an opportunity to deliver functional COL7 protein where it is needed – by intradermal administration in wounds of RDEB patients."

DeFi-RDEB is a multi-center, within-patient randomized, controlled, and open-label, Phase 3 trial designed to enroll approximately 24 participants. Each participant's target wounds are paired then randomized to receive D-Fi 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 three trial locations recruiting participants including Stanford University, Children's Hospital Colorado, and Dell Children's Medical Group in Austin, Texas. More information about the Phase 3 trial is available at ClinicalTrials.gov and searching the identifier NCT04213261.

The U.S. Food & Drug Administration (FDA) has granted regenerative medicine advanced therapy (RMAT), orphan drug, rare pediatric disease, and fast track designations for the development of D-Fi.

About D-Fi

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

About Castle Creek Biosciences

Castle Creek Biosciences, Inc. is a privately-held, clinical-stage cell and gene therapy company advancing innovative personalized therapies for underserved disorders with high unmet medical needs. The company is using its proprietary fibroblast technology platform to develop D-Fi (debcoemagene autoficel, formerly designated FCX-007), an investigational gene therapy for the localized treatment of wounds in dystrophic epidermolysis bullosa (DEB). The company is also developing FCX-013, an investigational gene therapy for the treatment of moderate to severe localized scleroderma. The company operates an in-house, current good manufacturing practices (cGMP), commercial-scale facility located in Exton, Pennsylvania. Castle Creek Biosciences is a portfolio company of Paragon Biosciences. For more information, visit castlecreekbio.com or follow Castle Creek on Twitter @CastleCreekBio.

About Paragon Biosciences

Paragon is a life science innovator that creates, invests in and builds life science companies in artificial intelligence, cell and gene therapy, synthetic biology and biopharmaceuticals. The company's current portfolio includes Castle Creek Biosciences, Emalex Biosciences, Evozyne, Harmony Biosciences, Qlarity Imaging, Skyline Biosciences, and a consistent flow of incubating companies created and supported by the replicable 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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