Castle Creek Biosciences Announces First Patient Dosed in Phase 1/2 Clinical Trial of FCX-013 Gene Therapy for Treatment of Moderate to Severe Localized Scleroderma

- Study targets a chronic autoimmune skin disorder affecting approximately 50,000 patients in the U.S. -

EXTON, PA – October 15, 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, announced that the first adult patient has been dosed in a Phase 1/2 clinical trial evaluating FCX-013, the company's investigational gene therapy, for the treatment of moderate to severe localized scleroderma.

"Dosing the first patient is an important milestone in the clinical development program for FCX-013, which we believe has the potential to be the first therapy to treat excessive collagen deposition at the site of localized scleroderma lesions in the skin and soft tissue," said John Maslowski, Chief Executive Officer of Castle Creek Biosciences. "Our hope is to relieve the debilitating, painful impact of localized scleroderma in patients who currently have limited treatment options."

Localized scleroderma is a chronic autoimmune skin disorder that leads to the excess production of collagen and causes thickening of the skin and connective tissue. In moderate to severe forms of the disorder, patients can experience discomfort, tightness and pain that limits their ability to function. Approximately 50,000 patients in the U.S. have moderate to severe localized scleroderma. Current treatment options include systemic or topical corticosteroids that target inflammation, UVA light therapy, and physical therapy. There are no U.S. Food and Drug Administration (FDA) approved therapies for patients living with this disorder.

"Localized scleroderma may be characterized based on the depth and pattern of lesions, and there are currently few treatment options to address the excessive collagen accumulation in the skin and connective tissue," said Mary Spellman, M.D., Chief Medical Officer of Castle Creek Biosciences. "With our proprietary fibroblast technology, we have an opportunity to develop and evaluate new personalized therapies that are designed for durability and formulated to be compatible with each patient's unique biology."

The open label, single cohort Phase 1/2 clinical trial is evaluating the safety of FCX-013 as its primary objective. Secondary objectives include assessments of fibrosis at targeted sclerotic lesions at various time points through 26 weeks post-administration of FCX-013. The trial will enroll up to 10 patients with moderate to severe localized scleroderma. More information about the Phase 1/2 trial is available at ClinicalTrials.gov and searching the identifier NCT03740724.

Castle Creek Biosciences is manufacturing FCX-013 at its in-house, current good manufacturing practices (cGMP), commercial-scale facility located in Exton, Pennsylvania.

About FCX-013

FCX-013 is Castle Creek Biosciences' investigational gene therapy candidate for the treatment of moderate to severe localized scleroderma. FCX-013 is an autologous fibroblast genetically modified using lentivirus and encoded for matrix metalloproteinase 1 (MMP-1), a protein responsible for breaking down collagen. FCX-013 incorporates a biologic switch activated by an orally administered compound to control protein expression at the site of the localized scleroderma lesions. FCX-013 is designed to be injected intradermally at the location of the fibrotic lesions where the genetically-modified fibroblast cells will produce MMP-1 to break down excess collagen accumulation. FCX-013 has been granted Orphan Drug, Rare Pediatric Disease and Fast Track designations by the FDA.

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/.

Media Contacts:
Adam Daley
Berry & Company Public Relations
614.580.2048
adaley@berrypr.com

Karen Casey
Castle Creek Biosciences
302.750.4675
kcasey@castlecreekbio.com

###