Fibrocell Announces Collaboration with Castle Creek Pharmaceuticals to Develop and Commercialize FCX-007 Gene Therapy

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- Fibrocell to receive up to $135 million, including up to $30 million in upfront, near-term and development payments and a 30% gross profit share -

- Fibrocell retains rights to the eligible Rare Pediatric Disease Priority Review Voucher -

- Phase 3 clinical trial (DEFI-RDEB) initiation expected in second quarter of 2019 -

- Fibrocell to host conference call at 8:30 AM EDT Today -

EXTON, Pa., April 15, 2019 (GLOBE NEWSWIRE) -- Fibrocell Science, Inc. (Nasdaq: FCSC), a cell and gene therapy company focused on transformational autologous cell-based therapies for skin and connective tissue diseases, today announced the completion of a collaboration agreement with Castle Creek Pharmaceuticals to develop and commercialize Fibrocell's lead gene therapy candidate, FCX-007, for the treatment of recessive dystrophic epidermolysis bullosa (RDEB), a rare, life-threatening genetic disorder diagnosed at infancy with no cure or treatment approved by the U.S. Food and Drug Administration (FDA).

"We are proud to partner with Castle Creek Pharmaceuticals, a company recognized for its innovation in drug development for rare skin diseases and its commitment to the epidermolysis bullosa community. This agreement provides resources and non-dilutive capital to continue the development and, if approved, commercialize FCX-007, a potentially transformative treatment for RDEB patients," said John Maslowski, President and Chief Executive Officer of Fibrocell. "With Castle Creek Pharmaceuticals providing funding for the development of FCX-007, Fibrocell can allocate additional resources to advance clinical development of FCX-013 for the treatment of moderate to severe localized scleroderma."

Under the terms of the collaboration agreement, Castle Creek Pharmaceuticals will receive an exclusive license to commercialize FCX-007 in the United States. Castle Creek Pharmaceuticals will be responsible for all development and manufacturing expenses up to $20 million prior to the initial Biologics License Application (BLA) filing with the FDA. If development spending exceeds $20 million, Castle Creek Pharmaceuticals will be responsible for 70% of the excess costs and Fibrocell will cover 30% of these additional expenses. Castle Creek Pharmaceuticals will also be responsible for all commercialization activities for FCX-007. Fibrocell will maintain responsibility for clinical development, regulatory interactions, and manufacturing of the product under a future supply agreement with Castle Creek Pharmaceuticals.

Fibrocell will receive an upfront payment of $7.5 million, $2.5 million for the first patient enrolled in the Phase 3 clinical trial and $30 million upon BLA approval and commercial readiness. Fibrocell is also eligible to receive up to $75 million in sales milestones, consisting of $25 million when FCX-007 achieves $250 million in cumulative net sales and an additional $50 million upon attaining $750 million in cumulative net sales. In addition, Castle Creek Pharmaceuticals will pay Fibrocell a 30% share of the gross profits from FCX-007 sales.

Fibrocell will retain sole ownership of the Rare Pediatric Disease Priority Review Voucher (PRV), which may be granted upon market approval of FCX-007. The PRV can be used to obtain priority review for a subsequent New Drug Application or BLA, and can be sold to another entity.

"We believe our collaboration with Fibrocell is synergistic and serves both of our long-term objectives well. It increases the breadth of Castle Creek's potential epidermolysis bullosa therapies by combining our clinical trial evaluating our investigational topical therapy (CCP-020) for epidermolysis bullosa simplex (EBS) with Fibrocell's gene therapy to potentially treat RDEB," said Greg Wujek, Chief Executive Officer of Castle Creek Pharmaceuticals. "Castle Creek values the contributions of the Fibrocell team in progressing development of FCX-007, and we are excited to work with them to continue advancing this novel EB therapy that offers the potential to bring relief to patients suffering from this chronic, painful and debilitating disease."

FCX-007 is a genetically-modified autologous fibroblast that encodes the gene for type VII collagen (COL7). In a recent Type B meeting, the FDA provided guidance on various design aspects of Fibrocell's proposed Phase 3 clinical trial, named DEFI-RDEB. The trial is designed as an open label, multi-centered, intra-patient controlled study expected to enroll 15-20 patients. The trial is expected to initiate in the second quarter of 2019.

FCX-007 is being developed in collaboration with Intrexon Corporation (Nasdaq: XON). As part of our existing Exclusive Channel Collaboration (ECC), Fibrocell will pay Intrexon 50% of all upfront, milestone, and profit share payments from Castle Creek Pharmaceuticals. Payments to Intrexon do not include funds received by Fibrocell from Castle Creek Pharmaceuticals in connection with the development and manufacturing costs or payments for supply of FCX-007. FCX-007's development continues subject to the 2012 ECC.

Based on Fibrocell's receipt of the upfront payment from Castle Creek Pharmaceuticals and reduction of expenses associated with the development of FCX-007, the Company believes its existing cash will be sufficient to fund operations into the third quarter of 2020.

In connection with the successful completion of the agreement with Castle Creek Pharmaceuticals, Fibrocell also concluded the strategic alternative review process announced last year. Canaccord Genuity Group, Inc. acted as financial advisor to Fibrocell.

Conference Call and Webcast
To participate on the live call, please dial 888-221-3881 (domestic) or +1-786-789-4776 (international), and provide the conference code 7350159 five to ten minutes before the start of the call. The conference call will also be webcast live under the investor relations section of Fibrocell's website at www.fibrocell.com/investors/events and will be archived there for 30 days following the call.

About FCX-007

FCX-007 is Fibrocell's clinical stage, gene therapy product candidate for the treatment of RDEB, a congenital and progressive orphan skin disease

caused by the deficiency of COL7. FCX-007 is a genetically-modified autologous fibroblast that encodes the gene for COL7. By genetically modifying autologous fibroblasts *ex vivo* to produce COL7, culturing them and then treating wounds locally via injection, FCX-007 offers the potential to address the underlying cause of the disease by providing high levels of COL7 directly to the affected areas while avoiding systemic distribution.

About FCX-013

FCX-013 is Fibrocell's clinical stage, 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 Intrexon's proprietary RheoSwitch Therapeutic System ®, a biologic switch activated by Veledimex—an orally administered compound—to control protein expression at the site of the localized scleroderma lesions. FCX013 is designed to be injected under the skin at the location of the fibrotic lesions where the genetically-modified fibroblast cells will produce MMP-1 to break down excess collagen accumulation.

About Fibrocell

Fibrocell is an autologous cell and gene therapy company translating personalized biologics into medical breakthroughs for diseases affecting the skin and connective tissue. Fibrocell's most advanced product candidate, FCX-007, is the subject of a Phase 1/2 clinical trial for the treatment of RDEB. Fibrocell is also developing FCX-013 for the treatment of moderate to severe localized scleroderma and is currently enrolling the Phase 1 portion of a Phase 1/2 clinical trial. For more information, visit www.fibrocell.com or follow Fibrocell on Twitter at @Fibrocell.

About Castle Creek Pharmaceuticals

Castle Creek Pharmaceuticals (CCP) is a privately held biopharmaceutical company developing innovative therapies for patients with rare, serious or debilitating dermatologic conditions. The company, with offices in Parsippany, New Jersey and Chicago, Illinois, is dedicated to developing and bringing novel therapies to those living with epidermolysis bullosa. For more information, visit: www.castlecreekpharma.com.

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Forward-Looking Statements

This press release contains, and our officers and representatives may from time to time make, statements that are "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. All statements that are not historical facts are hereby identified as forward-looking statements for this purpose and include, among others, statements relating to: Fibrocell's expectations regarding the timing and clinical development of FCX-007, including the Company's plans to initiate a Phase 3 clinical trial for FCX-007 in the second quarter of 2019; the potential benefits of the collaboration between Fibrocell and Castle Creek Pharmaceuticals; Fibrocell's potential to earn future milestone and profit share payments under the agreement with Castle Creek Pharmaceuticals; the expected trial design of DEFI-RDEB, and expectation to enroll 15-20 patients therein; the timing of our Phase 1/2 clinical trial of FCX-013, including our expectation to complete enrollment of Phase 1 adult patients in the third quarter of 2019; the potential advantages of FCX-007 and Fibrocell's other product candidates; the potential benefits of Fast Track Designation, Orphan Drug Designation and Rare Pediatric Disease Designation; the Company's belief that its cash and cash equivalents will be sufficient to fund operations into the third quarter of 2020 and other statements regarding Fibrocell's future operations, financial performance and financial position, prospects, strategies, objectives and other future events.

Forward-looking statements are based upon management's current expectations and assumptions and are subject to a number of risks, uncertainties and other factors that could cause actual results and events to differ materially and adversely from those indicated herein including, among others: Fibrocell has not yet received the FDA's official meeting minutes, and they may differ materially from the Company's understanding of the results of the Type B meeting with the FDA; the ability of Fibrocell and Castle Creek Pharmaceuticals to meet objectives tied to milestones and profit share payments; uncertainties and delays in the FDA review and approval of the clinical trial protocol for FCX-007; uncertainties and delays relating to the initiation, enrollment and completion of clinical trials; whether clinical trial results will validate and support the safety and efficacy of Fibrocell's product candidates; unanticipated or excess costs relating to the development of Fibrocell's gene therapy product candidates; Fibrocell's ability to obtain additional capital to continue to fund operations; uncertainties associated with being able to identify, evaluate and complete any strategic transaction or alternative; the impact of the announcement of the collaboration with Castle Creek Pharmaceuticals on the Company's business, including its financial and operating results; Fibrocell's ability to maintain its collaborations with Intrexon and Castle Creek Pharmaceuticals; Castle Creek Pharmaceuticals' ability to successfully commercialize FCX-007, if approved; and the risks, uncertainties and other factors discussed under the caption "Item 1A. Risk Factors" in Fibrocell's most recent Form 10-K filing and Form 10-Q filings. As a result, you are cautioned not to place undue reliance on any forward-looking statements. While Fibrocell may update certain forward-looking statements from time to time, Fibrocell specifically disclaims any obligation to do so, whether as a result of new information, future developments or otherwise.

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