Fibrocell Receives FDA Regenerative Medicine Advanced Therapy Designation for FCX-007 Gene Therapy for the Treatment of RDEB

May 29, 2019

EXTON, Pa., May 29, 2019 (GLOBE NEWSWIRE) -- Fibrocell Science, Inc. (Nasdaq: FCSC), a gene therapy company focused on transformational autologous cell-based therapies for skin and connective tissue diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted the Regenerative Medicine Advanced Therapy (RMAT) designation to FCX-007, the Company's gene therapy candidate for the treatment of recessive dystrophic epidermolysis bullosa (RDEB)—a devastating, genetic skin disease with high mortality.

Created under the 21st Century Cures Act, RMAT offers sponsors of cell and gene therapies eligibility for accelerated development and review of their product if it is intended to treat serious or life-threatening diseases and there is preliminary clinical evidence showing it has the potential to address unmet medical needs. This designation makes a product eligible for the same actions to expedite the development and review of a marketing application that are available to drugs that receive Breakthrough Therapy designation, including earlier and more frequent meetings with the FDA and potential eligibility for Priority Review and Accelerated Approval.

"We are pleased that the FDA has granted RMAT designation to FCX-007, which we believe offers the potential to address an unmet medical need of RDEB patients," said John Maslowski, President and Chief Executive Officer of Fibrocell. "We recognize this important designation has the potential to accelerate development and review of FCX-007, and we look forward to working closely with the FDA as our program advances into a Phase 3 clinical trial."

The Company expects to initiate the Phase 3 clinical trial for FCX-007 in the second quarter of 2019. Fibrocell projects enrollment and dosing of Phase 3 patients will be completed in the third quarter of 2020 and data collection for the primary endpoint will be completed in the fourth quarter of 2020. If the Phase 3 clinical trial is successful and completed within the projected timeframe, Fibrocell expects to file a Biologics License Application (BLA) for FCX-007 in 2021.

The RMAT designation augments the Orphan Drug, Rare Pediatric Disease and Fast Track designations previously granted to FCX-007 by the FDA.

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 the protein 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.

Fibrocell is developing FCX-007 in collaboration with Intrexon (Nasdaq: XON), a leader in synthetic biology. In addition, Fibrocell is working in collaboration with Castle Creek Pharmaceuticals to develop and commercialize FCX-007 for the treatment of RDEB. Castle Creek is recognized for its innovation in drug development for rare skin diseases and its commitment to bringing novel therapies to those living with epidermolysis bullosa.

About Recessive Dystrophic Epidermolysis Bullosa

RDEB is the most severe form of dystrophic epidermolysis bullosa (DEB), a congenital, progressive, devastatingly painful and debilitating genetic disorder that often leads to death. RDEB is caused by a mutation of the *COL7A1* gene, the gene which encodes for COL7, a protein that forms anchoring fibrils. Anchoring fibrils hold together the layers of skin, and without them, skin layers separate causing severe blistering, open wounds and scarring in response to friction, including normal daily activities like rubbing or scratching. Children who inherit the condition are often called "butterfly children" because their skin is as fragile as a butterfly's wings. Fibrocell estimates there are approximately 1,100 - 2,500 RDEB patients in the U.S. Currently, treatments for RDEB address only the sequelae, including daily bandaging, hydrogel dressings, antibiotics, feeding tubes and surgeries.

About Fibrocell

Fibrocell is a cell and gene therapy company focused on improving the lives of people with rare diseases of the skin and connective tissue. The Company is utilizing its proprietary autologous fibroblast technology to develop personalized biologics that target the underlying cause of disease. Fibrocell's pipeline of localized gene therapy candidates include FCX-007 for the treatment of RDEB, a life-threatening genetic disorder diagnosed in infancy with no cure or treatment approved by the FDA. A pivotal Phase 3 clinical trial for FCX-007 is planned for the second quarter of 2019. 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 us on Twitter at @Fibrocell.

Trademarks

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 expected trial design of DEFI-RDEB, and expectation to enroll 15-20 patients therein; Fibrocell's projection to complete enrollment and

dosing of FCX-007 Phase 3 patients in the third quarter of 2020 and complete data collection for the primary endpoint in the fourth quarter of 2020; Fibrocell's expectation to file a BLA for FCX-007 in 2021; the potential advantages of FCX-007, FCX-013 and Fibrocell's other product candidates; the potential benefits of an RMAT designation, Fast Track designation, Orphan Drug designation and Rare Pediatric Disease designation; 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: 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; 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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