Fibrocell Announces FDA Fast Track Designation of FCX-007 for Treatment of Recessive Dystrophic Epidermolysis Bullosa

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EXTON, Pa., Jan. 05, 2017 (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 Fast Track designation to FCX-007, the Company's clinical-stage candidate for the treatment of Recessive Dystrophic Epidermolysis Bullosa (RDEB)—a rare, devastating genetic skin disease for which no FDA-approved therapies exist.

"Fast Track designation represents a significant milestone in advancing clinical development of FCX-007 for the treatment of RDEB," said John Maslowski, Chief Executive Officer of Fibrocell. "We are pleased the Agency has awarded this designation to FCX-007 which, we believe, has the potential to be the first gene therapy to treat the underlying cause of RDEB and to bring relief to patients suffering from this debilitating, painful disease."

The Fast Track program is designed to facilitate development and expedite review of new therapies that address unmet medical needs of patients with serious conditions. The designation offers various benefits, including more frequent meetings with the FDA to discuss the drug's development plan, eligibility for Accelerated Approval or Priority Review if relevant criteria are met, and opportunity for Rolling Review, which allows the Company to submit completed sections of its Biologics License Application (BLA) to the FDA, rather than waiting until every section of the BLA is completed before the entire application can be reviewed.

FCX-007 was previously granted Orphan Designation by the FDA for the treatment of Dystrophic Epidermolysis Bullosa (DEB), which includes RDEB, and Rare Pediatric Disease Designation by the FDA for treatment of RDEB.

Fibrocell is developing FCX-007 in collaboration with Intrexon Corporation (NYSE:XON), a leader in synthetic biology.

About FCX-007

FCX-007 is Fibrocell's clinical-stage, gene-therapy product candidate for the treatment of recessive dystrophic epidermolysis bullosa (RDEB), a congenital and progressive orphan skin disease caused by the deficiency of the protein type VII collagen (COL7). FCX-007 is a genetically-modified autologous fibroblast that encodes the gene for COL7 and is being developed in collaboration with Intrexon Corporation. 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 Recessive Dystrophic Epidermolysis Bullosa (RDEB)

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 type VII collagen, 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. We estimate 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 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, has begun a Phase I/II trial for the treatment of recessive dystrophic epidermolysis bullosa (RDEB). Fibrocell is in pre-clinical development of FCX-013, its product candidate for the treatment of linear scleroderma. In addition, Fibrocell has a third program in the research phase for the treatment of arthritis and related conditions. Fibrocell's gene-therapy portfolio is being developed in collaboration with Intrexon Corporation (NYSE:XON), a leader in synthetic biology. For more information, visit www.fibrocell.com or follow us on Twitter at @Fibrocell.

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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: the potential advantages of FCX-007 and Fibrocell's other product candidates; the potential benefits of Fast Track Designation, Orphan 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 relating to the initiation, enrollment and completion of pre-clinical and clinical trials; whether pre-clinical and clinical trial results will validate and support the safety and efficacy of Fibrocell's product candidates; Fibrocell's ability to obtain additional capital to continue to fund operations; Fibrocell's ability to maintain its collaboration with Intrexon Corporation 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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