Fibrocell Announces Positive Feedback from Type B End-of-Phase 2 Meeting with FDA on Phase 3 Clinical Trial Design for FCX-007

March 27, 2019

- Phase 3 clinical trial, named DEFI-RDEB, is expected to commence in the second quarter of 2019 -

- Additional data from Phase 1/2 clinical trial demonstrates FCX-007 continues to be well tolerated with continued positive trends in wound healing -

- Company reports full year 2018 financial results -

- Conference call & webcast scheduled at 8:30 a.m. EDT today -

EXTON, Pa., March 27, 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 the completion of a Type B end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) to discuss the design of a Phase 3 clinical trial for FCX-007, the Company's gene therapy candidate for the treatment of recessive dystrophic epidermolysis bullosa (RDEB), to support a Biologics License Application (BLA) filing. In addition, the Company reported additional positive safety and wound healing data from its ongoing Phase 1/2 clinical trial of FCX-007.

FCX-007 Phase 3 Trial Design and FDA Type B Meeting Feedback

In the Type B face-to-face meeting, the FDA provided guidance on various design aspects of Fibrocell's proposed Phase 3 clinical trial, named DEFI-RDEB (***de****rmal* ***fi****broblasts-****RDEB***). The trial is designed as an open label, multi-centered, intra-patient controlled trial expected to enroll 15-20 patients. Selected wounds will be monitored prior to dosing to confirm they are non-healing. For each patient, up to three pairs of wounds will be identified at baseline and randomized, with one wound receiving FCX-007 and the other wound left as the untreated control. Two doses of FCX-007 will be administered four weeks apart to the treated wounds. Both treated and untreated wounds will also receive standard of care, including routine skin care and bandaging.

The proposed primary outcome measure for the DEFI-RDEB trial is a comparison of the proportion of FCX-007 treated wounds and untreated matched wounds with complete closure in a prospectively defined wound pair at 12 weeks post-administration of the first dose. Secondary endpoints include evaluation of the proportion of wounds achieving >50% wound closure, a patient reported outcome measure and an analysis of durability out to 24 weeks. The presence of type VII collagen (COL7) will be assessed from biopsy samples in a subpopulation of patients as an exploratory endpoint.

Fibrocell plans to submit a revised clinical trial protocol and statistical analysis plan based upon the FDA's feedback and requested Chemistry, Manufacturing and Controls (CMC) information to the Investigational New Drug (IND) application.

"The FDA has provided us with invaluable advice on the design of the DEFI-RDEB trial, and we are grateful for their comprehensive feedback," said John Maslowski, President and Chief Executive Officer of Fibrocell. "RDEB remains an urgent unmet medical need, and we believe the initiation of a Phase 3 clinical trial of FCX-007 for this devastating disease is a significant milestone for both patients and Fibrocell. We are working diligently to incorporate the FDA's comments into the IND, with the expectation of initiating the Phase 3 trial in the second quarter of 2019."

FCX-007 Phase 1/2 Trial Update

Fibrocell also reported today updated data from its ongoing Phase 1/2 clinical trial for FCX-007. To date, FCX-007 has been evaluated in eight wounds across five adult RDEB patients in the trial. Consistent with previously reported results, no product-related serious adverse events or circulating autoantibodies to COL7 have been reported.

The proportion of wounds healing at increasing closure percentages 12-week post-administration of a single injection session of FCX-007 are as follows:

	Wound Closure Percentage		
	>50%	**>75%**	**Complete**
FCX-007 Treated Wounds	88% (7/8)	75% (6/8)	63% (5/8)
Untreated Control Wounds	29% (2/7)	14% (1/7)	0% (0/7)

The complete wound closure result (63% treated vs. 0% untreated) was the basis for the primary endpoint design in the DEFI-RDEB trial.

The proportion of wounds with >50% closure at various post-administration visits are as follows:

	Study Visit			
	4 Weeks	**12 Weeks**	**25 Weeks**	**52 Weeks**
FCX-007 Treated Wounds	100% (8/8)	88% (7/8)	67% (2/3)	66% (2/3)
Untreated Control Wounds	13% (1/8)	29% (2/7)	0% (0/2)	33% (1/3)

"We continue to be encouraged by the positive safety and efficacy trends for FCX-007", stated Alfred Lane, MD, Chief Medical Advisor of Fibrocell and

Professor of Dermatology and Pediatrics (Emeritus) at the Stanford University School of Medicine, “As the FDA has provided the necessary feedback to design a Phase 3 trial for FCX-007, we look forward to determining the potential benefits to patients suffering with RDEB.”

Fibrocell recently completed dosing of a sixth patient—the first pediatric patient dosed with FCX-007—in the current Phase 1/2 clinical trial Remaining Phase 2 patients who have not received dosing will be contacted to determine if they would agree to reconsent into the Phase 3 trial.

As a reminder, the FDA has granted Orphan Drug Designation, Rare Pediatric Disease Designation and Fast Track Designation to FCX-007.

Fibrocell is also developing FCX-013 for the treatment of moderate to severe localized scleroderma. Fibrocell reported FCX-013 received Fast Track Designation from the FDA in the third quarter of 2018, and its IND for this gene therapy candidate was granted allowance by the FDA earlier in the year. Fibrocell is currently enrolling the Phase 1 portion of a Phase 1/2 clinical trial for FCX-013, and expects to complete enrollment of Phase 1 adult patients in the third quarter of 2019. In addition to the Fast Track Designation, FCX-013 has also been granted Orphan Drug and Rare Pediatric Disease Designations by the FDA.

Financial Results for the Twelve Months Ended December 31, 2018

For the year ended December 31, 2018, Fibrocell reported a diluted net loss of $1.45 per share, compared to a diluted net loss of $6.67 per share for the same period in 2017.

Research and development expenses decreased 51% to approximately $6.0 million for the year ended December 31, 2018, as compared to approximately $12.2 million for the same period in 2017. The decrease in FCX-007 spending was due primarily to decreased costs from our clinical partner Intrexon Corporation, as the Phase 1 portion of the FCX-007 Phase 1/2 clinical trial was substantially completed at the end of 2017; movement in-house of the manufacturing of the drug product used in the Phase 1/2 clinical trial of FCX-007 previously contracted to a third party manufacturer and a decrease of approximately $0.5 million in an estimate of costs to settle a dispute with one of Intrexon’s vendors, for which a settlement was agreed to and was paid by us in August 2018. The decrease in FCX-013 spending was related primarily to decreased costs from Intrexon of approximately $2.3 million, as substantially all of the costs of the pre-clinical phase of the FCX-013 program were incurred at the end of 2017, while 2018 has been used for clinical trial start-up activities.

Fibrocell used approximately $12.7 million in cash for operations during the year ended December 31, 2018, and used approximately $17.0 million in cash for operations during the year ended December 31, 2017.

As of December 31, 2018, the Company had cash and cash equivalents of approximately $14.4 million and working capital of approximately $12.4 million. The Company believes that its cash and cash equivalents will be sufficient to fund operations into the fourth quarter of 2019.

Conference Call and Webcast

To participate on the live call, please dial 888-394-8218 (domestic) or +1-323-794-2588 (international), and provide the conference code 8315981 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 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 Corporation (Nasdaq: XON), a leader in synthetic biology. Fibrocell manufactures clinical supply of FCX-007 and, if approved, plans to conduct future commercial manufacture of FCX-007 at its cGMP manufacturing facility located in Exton, Pennsylvania. Fibrocell’s multi-product gene therapy manufacturing facility in Exton has sufficient vector supply to complete the Company’s clinical trials and existing manufacturing capacity to serve the U.S. market for RDEB.

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.

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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 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 fourth quarter of 2019 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; 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 Board of Directors' review of strategic alternatives, as well as any strategic transaction or alternative that may be pursued, on the Company's business, including its financial and operating results and its employees; Fibrocell's ability to maintain its collaboration with Intrexon; 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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