



U.S. FDA Approves Removal of “Not for Home Use” Label Restriction for Pliaglis®

LAVAL, QC, December 17, 2018 /CNW/ - Crescita Therapeutics Inc. (TSX: CTX) (Crescita or the Company), a Canadian commercial dermatology company with a portfolio of non-prescription skincare products and prescription drug products for the treatment and care of skin conditions, diseases and their symptoms, is pleased to announce that the U.S. Food and Drug Administration (FDA) has approved the Prior Approval Supplement (PAS) for Pliaglis® following its mandated six-month review process, in line with the target action date under the Prescription Drug User Fee Act (PDUFA).

In 2017, Taro Pharmaceuticals Inc. (Taro), our licensee for Pliaglis in the U.S. market, completed the study to support the removal of the Pliaglis “Not for Home Use” label restriction and filed the FDA submission with the proposed label change on June 8, 2018. The removal of the “Not for Home Use” label restriction is accompanied by the addition of a new user instruction sheet and product applicator. The approval of this submission triggers a milestone of US\$0.5 million for Crescita.

“We are delighted with the approval of this label change by the FDA. It marks a significant milestone as it will expand the ability of patients to have access to the drug and will facilitate our partner’s efforts to increase market acceptance of Pliaglis in the U.S.” said Serge Verreault, President and Chief Executive Officer of Crescita.

About Pliaglis®

Pliaglis, a lidocaine and tetracaine (7%/7%) formulation, is a U.S. FDA approved topical local anesthetic cream that provides safe and effective local dermal anesthesia on intact skin prior to superficial dermatological procedures, such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing and laser-assisted tattoo removal. This product contains lidocaine and tetracaine and utilizes the proprietary phase-changing topical cream “Peel” technology. The “Peel” technology consists of a drug containing cream which, once applied to a patient’s skin, dries to form a pliable layer that releases drug into the skin. Following the application period, Pliaglis forms a pliable layer that is removed from the skin allowing the dermatological procedure to be performed with minimal to no pain.

About Taro Pharmaceutical Industries Ltd.

Taro (NYSE: TARO) is a multinational, science-based pharmaceutical company, dedicated to meeting the needs of its customers through the discovery, development, manufacturing and marketing of the highest quality healthcare products. For further information on Taro, please visit the Company’s website at www.taro.com.

Out-licensing Agreement with Taro Pharmaceuticals Inc.

On April 25, 2017, the Company entered into a Development and Commercialization License Agreement (“the Agreement”) with Taro Pharmaceuticals Inc. Under the terms of the Agreement, Crescita granted Taro an exclusive license to sell and distribute Pliaglis and Flexicaine in the U.S. market. Crescita retained all rights to Pliaglis in Canada and Mexico and continues to explore alternatives for the preferred commercial distribution pathway for Pliaglis in these territories. During the first quarter of 2018, the Company announced that the product was launched in the U.S. by Taro.

About Crescita Therapeutics Inc.

Crescita (TSX: CTX) is a publicly traded, Canadian commercial dermatology company with a portfolio of non-prescription skincare products and prescription drug products for the treatment and care of skin conditions and diseases and their symptoms. Crescita owns multiple proprietary drug delivery platforms that support the development of patented formulations that can facilitate the delivery of active drugs into or through the skin. For additional information, please visit www.crescitatherapeutics.com.

Forward-Looking Statements

This Press Release contains “forward-looking statements” within the meaning of applicable securities laws. Forward-looking statements can be identified by words such as: “anticipate,” “intend,” “plan,” “goal,” “seek,” “believe,” “project,” “estimate,” “expect,” “strategy,” “future,” “likely,” “may,” “should,” “will” and similar references to future periods. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on the Company’s current beliefs, expectations and assumptions, the future of its business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of the Company’s control. Crescita’s actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, readers should not rely on any of these forward-looking statements. Important factors that could cause Crescita’s actual results and financial condition to differ materially from those indicated in the forward-looking statements include, the risk factors included in Crescita’s most recent Annual Information Form dated March 27, 2018 under the heading “Risks Factors”, and as described from time to time in the reports and disclosure documents filed by Crescita with Canadian securities regulatory agencies and commissions. These and other factors should be considered carefully, and readers should not place undue reliance on Crescita’s forward-looking statements. As a result of the foregoing and other factors, no assurance can be given as to any such future results, levels of activity or achievements and none of Crescita or any other person assumes responsibility for the accuracy and completeness of these forward-looking statements. Any forward-looking statement made by the Company in this Press Release is based only on information currently available to it and speaks only as of the date on which it is made. Except as required by applicable securities laws, Crescita undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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