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FDA approves Calcitriol’s new contract manufacturing submission

17 July 2018 | News

This approval was necessary in order to market and commercialize Calcitriol in the United States.

Singapore – Rockwell Medical provided an update regarding Calcitriol, the Company's FDA approved active vitamin D injection for the management of hypocalcemia in patients undergoing chronic hemodialysis.

On July 11, 2018, Rockwell Medical received FDA approval of its Prior Approval Supplement for manufacturing Calcitriol. This approval was necessary in order to market and commercialize Calcitriol in the United States. Calcitriol is FDA approved under an Abbreviated New Drug Application and is manufactured through a contract manufacturing organization ("CMO"). As previously announced, the Company submitted a manufacturing update to the FDA to approve the CMO and the FDA had provided a target date for a response to Rockwell Medical's submission no later than August 19, 2018.

The Company will provide additional information regarding its plans for commercial production and sales of Calcitriol in the United States as it moves forward. The Company does not expect Calcitriol sales to have a material impact on its total revenue for 2018.