

Thermo Fisher Scientific Designs Flexible Manufacturing Site for Flexion Therapeutics, Inc.

Customized Manufacturing Suite Installed at UK site to produce Zilretta™

DURHAM, N.C., Jan. 11, 2018 /[PRNewswire](#)/ -- Thermo Fisher Scientific Inc., the world leader in serving science, announced today that manufacturing of Zilretta™, is underway at its Swindon, U.K. site where a custom "condo" manufacturing suite has been installed to support the launch of Flexion's newly approved therapy for osteoarthritis-related knee pain.

The condo was designed specifically for Flexion's needs – providing the ideal environment for complex formulations and create a manufacturing runway from development to commercialization.

Zilretta™ (triamcinolone acetonide extended-release injectable suspension) is the first and only FDA-approved extended-release intra-articular therapy for patients experiencing osteoarthritis-related knee pain. Zilretta™ employs proprietary microsphere technology combining triamcinolone acetonide — a commonly administered, short-acting corticosteroid — with a poly lactic-co-glycolic acid (PLGA) matrix to provide extended pain relief over 12 weeks.

Flexion selected the Patheon custom manufacturing solution to meet the anticipated demand for this innovative treatment for osteoarthritis knee pain. Under this "condo" arrangement, Flexion benefits from a dedicated manufacturing operation that can operate as needed to meet supply requirements while sharing high-cost capital and operating expense functions.

"We knew going into the launch of this novel therapy that it was critical to have the capacity to respond to increases in demand for our medicine," said Michael Clayman, D.D., president and chief executive officer of Flexion. "The strategic solution provided by Thermo Fisher's Pharma Services business creates flexibility to ensure supply."

According to industry analysts, the rapidly changing pharmaceutical landscape presents tremendous challenges for companies to accurately forecast demand.¹ To address this, Thermo Fisher's Pharma Services business develops unique solutions and business models providing flexible manufacturing options to address client needs in an evolving marketplace.

"This condominium suite created with and for Flexion is a tangible example of out-of-the-box thinking in the pharmaceutical services industry," said Michel Lagarde, president of pharma services for Thermo Fisher Scientific. "These flexible capacity solutions require a strategic and collaborative approach – different from the traditional 'price per batch' concept. This condominium suite created with Flexion is a departure from the 'build or buy' paradigm and represents a superior value for our clients."

About Thermo Fisher Scientific

Thermo Fisher Scientific Inc. is the world leader in serving science, with revenues of \$20 billion and more than 65,000 employees globally. Our mission is to enable our customers to make the world healthier, cleaner and safer. We help our customers accelerate life sciences research, solve complex analytical challenges, improve patient diagnostics, deliver medicines to market and increase laboratory productivity. Through our premier brands – Thermo Scientific, Applied Biosystems, Invitrogen, Fisher Scientific and Unity Lab Services – we offer an unmatched combination of innovative technologies, purchasing convenience and comprehensive support. For more information, please visit www.thermofisher.com.


iORC International, 2016 *Implications for Inaccurate Forecasting on Biologics Drug Substance Manufacturing*, 12.

"Why is it so hard to predict sales of new drugs?" Forbes, Oct.2013

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