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Piramal to Invest $10M Over the Next Year in Their Aseptic Manufacturing Facility in Lexington, Kentucky

Piramal Enterprises, one of the world's leading Contract Development and Manufacturing Organizations (CDMOs) has plans to expand its aseptic manufacturing facility in Lexington, Kentucky. The site is operated as a wholly owned subsidiary Coldstream Laboratories, Inc., which is a speciality contract developer and manufacturer of sterile injectable products. Earlier this year, in January, Piramal Enterprises acquired Coldstream Laboratories for $30 million. The company has now approved a $10 million investment in the expansion of Coldstream's 22,000-square-foot, stateof-the-art, FDA-inspected manufacturing facility that was built in 2006. Coldstream has engaged an engineering firm to design the expansion of its manufacturing facility by adding a third filling line and a new filling suite. With this expansion, Coldstream is poised to take advantage of the ever-increasing demand for its services. To date, Coldstream has developed and manufactured over 150 sterile products for more than 135 pharmaceutical and biotech customers.

Sterile Injectable Market
The global sterile injectable market was estimated to be approximately $312 billion in 2014 and is projected to reach $363 billion by 2017. The two largest segments are biologics (52 percent share) and small molecule products (38 percent share). One of the primary drivers behind the growth in the injectables space is the demand for generic products. Growth in the annual sales of generic injectables is outpacing growth in innovative new products. The global, generic, sterile injectables market is projected to grow from $37 billion in 2013 to $70 billion in 2020, an annual growth rate of 10 percent (Source: DCAT Value Chain Insights). Another significant factor driving the growth of the injectable market is the emergence of novel drug delivery systems like liposomes, nanoformulations and depot injections, among others, which offer improved disease targeting and better patient compliance.

Coldstream — Piramal Capabilities
The acquisition of Coldstream by Piramal allows the combined entity to leverage each organization's unique strengths in a way to offer enhanced value to its customers. With these acquired capabilities, Piramal now joins a small group of CDMOs offering integrated development and manufacture of API and finished products, but is the only CDMO offering an end-to-end solution for antibody- drug conjugate (ADC) products. Coldstream now has access to Piramal's strong formulation development capabilities, a highly experienced regulatory team, and a global supply network. Piramal can leverage its sterile formulation development site in Mumbai, India and its specialty ADC capabilities in Grangemouth, Scotland with Coldstream's capabilities for clinical and commercial sterile injectable supply. The clinical packaging, kit assembly, randomization and labelling services are offered from Piramal's site in Morpeth, U.K.

Our End-to-End Sterile Formulation Capabilities:

Formulation Development (Mumbai, India and Coldstream, USA Facilities)
• Pre-Formulation Studies.
• Formulation Development.
• Analytical Method Development and Validation.
• Lyophilization Development.
• Microbial Tests.
• Full ICH Stability Studies.

Clinical Trial Support Services (Clinical Trial Packaging — Morpeth, U.K. Facility; Clinical Trial Manufacturing — Coldstream, USA Facility)
• Clinical Phase I - III Manufacturing And Packaging:

o Animal Safety/Toxicity Studies.
o Human Clinical Products.
o Veterinary Products.

Commercial Manufacturing (Coldstream, USA Facility)
• Parenteral Sterile Fill/Finish.
• Parenteral Lyophilization.
• Cytotoxic and Potent Compounds.

For more information, please visit www.piramalpharmasolutions.com or stop by Booth #336.

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