

FDA and MHRA approvals spur ADC growth agenda for Piramal Grangemouth

Mumbai, May 1, 2012: Since 2011's CPhI Worldwide, Piramal Healthcare (Stand 4F16) at Grangemouth have had an eventful and hugely successful year.

The site gained FDA approval for its Antibody Drug Conjugation (ADC) facility in June 2011 - meaning that the site was the first ADC CMO to host a successful FDA Inspection, becoming the world's first contract supplier at commercial scale for ADCs.

This was on the back of an upgrade programme – started in 2006 - that saw the company invest US \$400k. on an upgraded QC laboratory and a total of US \$800k. on ADC manufacturing facilities since 2008.

The immediate outcome from the inspection was that Piramal's client were able to gain BLA approval from the FDA two weeks ahead of schedule and were immediately approved to supply commercial scale ADCs for onward fill/finishing.

After recruiting an EU Qualified Person into the site Head of Quality position, Grangemouth then submitted Manufacturing Licence applications to MHRA and - following a successful MHRA inspection in May 2012 - the site was also approved for EU commercial scale supply.

These key milestones have generated significant interest in the ADC sector as they demonstrate Piramal's ability to meet internationally recognised cGMPs and be ready for inspection.

Grangemouth continues to build on a notable track record in both ADC development and scale-up production. Piramal's facility is one of only a handful in the contract manufacturing sector to offer the needed combination of expertise in handling highly potent compounds, conventional pharma synthesis and bioprocessing multi-scale capabilities at a single, fully integrated production site.

“These achievements represent how effective the Grangemouth team have been in analysing and interpreting the needs of clients and putting in place GMP processes that are reliable, predictable and appropriately designed to meet cGMPs” said John Johnson, Piramal Healthcare UK's Quality Director.

Terry Cooke, Grangemouth's Site Leader added: “We are very proud to be seen as an extension of our customer's organisations and are continually exploring new ways to differentiate our offering to clients. The quality and experience within our team means that



we can offer unparalleled advice, partnership in project management, technical support and predictable delivery to key milestones”.

Piramal Healthcare have already seen a favourable increase in client enquiries as the ADC sector begins to move into late phase development and commercialisation of novel molecules.

Following a visit earlier this year by Scotland’s Deputy First Minister Nicola Sturgeon MSP - centrepiece of the formal opening of the upgraded manufacturing suite and QC laboratory - the site is now prepared for long term sustainable growth and increased collaborations with the world’s leading ADC companies.

Already in the global top 10 of CMOs, Piramal Healthcare is targeting to be world number three by 2016/17, driven by organic growth and the benefit from any strategic acquisitions in the space. About Piramal Healthcare

Piramal Healthcare is a part of the Piramal Enterprises Ltd. Led by Ajay G. Piramal, the Piramal Group is one of India’s foremost business conglomerates. Emerging from a rich textile industry lineage, the Piramal Group has exemplified diversification by foraying into a myriad of industries that encompass healthcare, drug discovery and research, glass, real estate and financial services.

Piramal Enterprises, Piramal Life Sciences, Piramal Glass and Piramal Realty are the flagship companies that operate within these sectors. The Piramal Group truly demonstrates a global footprint with its products and services being exported to over 100 countries, its international income contributing to greater than 70% of the Group’s revenues and more than 15 nationalities being represented amongst its employees.