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Piramal Forward Integrates to Become a Full-Service CDMO in the Field of ADCs

Article Courtesy of Piramal

Manufacturing of Antibody Drug Conjugations (ADCs) is not only complex from a process/technical point of view, but also struggles with challenges posed from managing a complicated supply-chain requirement. In many cases, development organizations must manage as many as five service providers for the development and manufacture of their clinical candidates — high-potent molecules (“payloads”), chemical linkers, monoclonal antibodies, conjugation step and drug product manufacturing. Current CDMOs are adapting to a sudden increase in demand while also responding to rapid developments in cytotoxins, linking chemistries and antibody designs for the next generation of ADCs.

While the ADC market is fast evolving on the technical side, business deals and alliances are further shaping this fluid market. Monoclonal antibody players have jumped onto the bandwagon, seeking to offer new antibodies to the ADC development organizations and expanding the number of products being developed. As a result of the technical advances and alliances in this market, the ADC segment is anticipated to be as big as a MAB market in near future.

ADC Market

The global ADC market resulted in \$500 million in sales in 2014, achieved by the only two ADC products. Sales of the currently marketed ADC products are anticipated to grow by 33 percent CAGR (2013-2024) and will exceed \$9 billion in sales by 2024. Current estimates indicate there are about 100 products in active development, of which more than 50 percent were added in and after 2012. Around 38 products are in clinical phase, clearly signifying a growing interest in ADC products. By 2019, a total of eight ADCs are expected to be approved for commercial sale in the U.S. by the FDA.

Almost all of the bioconjugation manufacturing and fill/finish activities are outsourced. The global ADC CDMO market in 2013 was valued at \$67 million and was projected to rise at a CAGR of 29 percent to \$1 billion by 2024. The largest segment of the CDMO market lies in the development and manufacture of MAbs (about 60 percent), while the conjugation and fill/finish services enjoy an equal share of approximately 20 percent each. (Source: ADC Contract Manufacturing Market 2014 – 2024, Roots Analysis)

Piramal ADC Capabilities

Piramal has the capability to manufacture batches with MAbs input sizes of up to 2.5 kilograms out of its facilities in Grangemouth Scotland. Acquired by Piramal in 2005, this facility has over a decade of experience working on over 130 ADC projects covering more than 40 different payloads and a variety of different antibody types. Piramal Grangemouth claims unparalleled experience in the development and manufacture of ADCs and is one of the few commercially approved manufacturing sites for ADC products. Since entry into the ADC business in 2005, we have manufactured over 600 batches of ADC products, including over 300 GMP clinical or commercial batches. We have experience working with all of the major drug platforms including auristatins, maytansines, PBDs, duocarmycins as well as non-cytotoxic payloads. We have a world-recognized expertise for development of cell-based killing assays. We offer a wide range of analytical services supporting all phases of method development and validation with the ability to support your ICH stability studies as well.

Piramal's Expansion

With the acquisition of Coldstream Laboratories in Lexington, Kentucky this past January, Piramal now offers a complete solution, from the development and manufacture of the ADC bulk drug substance to the sterile filling of liquid and lyophilized ADC finished drug products. We have plans to expand the capabilities of our sterile fill/finish facility in Lexington, introducing a third filling line and a new filling suite by early 2017.

In February of this year, we received MHRA approval for a new state-of-the-art ADC commercial manufacturing suite in Grangemouth to add to the two existing suites. Further expansion of our Grangemouth facilities is being planned to increase the current batch capacity from 2.5 kilograms toward 5 kilograms over the next 2- 5 years. This will strengthen Piramal's position as one of the premier CDMOs for the manufacture of commercial ADCs.

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

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