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LONDON, UK (GlobalData), 25 June 2012 - The **in-vitro diagnostic industry** is witnessing **companion diagnostics** emerge as the **next big thing**, as attention in the pharmaceutical industry shifts from blockbuster drugs to personalized medical treatment, says a new report by healthcare experts GlobalData.

The new report* states that the companion diagnostics industry is being spurred on as the pharmaceutical industry faces increasing development costs and stringent regulatory approval processes in the blockbuster model of drug development. Companies are therefore changing their focus to personalized medicine, looking to provide pharmaceuticals specifically designed for a patient's genetic constitution.

Companion diagnostics assess a patient's response to certain therapies using biomarkers. This enables disease risk prediction, disease diagnosis, and monitoring of treatment progress. Theranostics is a category of companion diagnostic tests developed to identify patient populations exhibiting the most favorable responses to a therapeutic drug, and to monitor drug activity inside a patient's body. For instance, BRCA1 and BRCA2 tests can help identify patients who are genetically susceptible to breast cancer.

Companion diagnostics benefit the pharmaceutical industry by reducing drug development from 10-12 years to 5-7 years, and shrinking overall development costs from around $1 billion to less than $500m, as a select target patient population can be used in testing to provide more accurate clinical trial results.

The companion diagnostic industry is currently focused heavily on oncology, as developments in molecular biology led to the discovery of new biomarkers for oncology treatment. The industry is also under increasing pressure from regulatory bodies to provide more credible clinical results for expensive cancer drug therapies, and companion diagnostics can offer a higher probability of better treatments.

Many pharmaceutical companies are looking to partner with a diagnostic development company that can help select a perfect target audience for their drug. A favorable regulatory environment in the US and Europe is helping to support these collaborations, and regulatory agencies such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have acknowledged the benefits offered by personalized medicines. The growing confidence in companion diagnostics can be witnessed in the collaboration between the US FDA, the EMA and Japanese regulatory authorities, along with 16 leading pharmaceutical companies, to approve a new biomarker test for kidney damage. The cooperation was facilitated by an independent third party; Critical Path Institute (C-PATH), with whom the pharmaceutical companies agreed to share confidential proprietary clinical data to help identify useful biomarkers. The cooperation project led to the first ever joint submission to both the US FDA and the EMA in 2007, and its subsequent approval in 2008. Such cooperation and harmonization among regulatory bodies shows promise for the future companion diagnostics.

The companion diagnostics market was valued at $790m in 2011 and is expected to grow at a CAGR of 21.3% during 2011-2018, due to an increase in a high number of companion diagnostics deals, a positive regulatory environment, and increasing focus of pharmaceutical companies on personalized medicines.