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The pharmaceutical industry is driven by innovation in drug discovery. The age of the blockbuster drug looks to have ended, with the return on R&D spend having declined 6.4% between 2010 and 2016, according to GlobalData's Pharmaceutical Products Database .

Jamie Goodman, Senior Healthcare Analyst at GlobalData believes that "Specialization and treatment of unmet need is the new paradigm, with companies finding greatest success in therapy area focus and development of novel therapies for niche diseases. The market landscape has become broader, deeper and far more intricate in recent years, and is set to continue. Access to detailed drug insight, the milestones, decisions and events in a drug's lifetime are more vital than ever in understanding the dynamics of the industry and drivers of success".

Pursuit of novel treatment mechanisms and a drive towards personalized medicine has created a highly diverse drug pipeline with successful launch and promising initial outcomes of the first Immuno-Oncology products. The pipeline has exploded with development programs looking to compete with the pioneering checkpoint inhibitors Yervoy, Opdivo and Keytruda and cell therapy Provenge. Careful tracking and analysis of the R&D detail will be necessary to understand the success factors as these development programs mature.

The regulatory environment is adapting to the needs of drug developer and patient, providing alternative pathways to approval and influencing market access strategies. Review designations such as FDA Breakthrough Therapy, EMA PRIME and PMDA Sakigake are being awarded with greater frequency and are contributing to a pipeline focused on the treatment of unmet needs.

Companies are realizing the opportunity in niche drug development. Although small, orphan diseases provide markets with few competitors and more pathways to approval. An increased focus on intelligent market access strategy has resulted in pursuit of greater emphasis on thoughtful selection of product indication.

Goodman concludes: "Companies are recognizing that innovation is more necessary than ever in ensuring return on investment. Niche drug development and perusal of alternative pathways

and regulatory designations have proved popular strategies, with over 2,100 products having been awarded a review designation by the US FDA, and over 2,000 unique indications with at least one drug in development. The explosion of the Immuno-Oncology pipeline has demonstrated that innovative drug design is the key to winning big”