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# Life in the fast lane: Developing and commercializing KEYTRUDA®, a novel breakthrough therapy designation oncology therapy, in three years from first patient dosed to US approval

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In order to accelerate the availability of novel potentially life-saving therapies, the FDA has developed multiple programs, including recently assigning breakthrough therapy designation to promising candidates in development. At the time of breakthrough therapy designation, Merck had only manufactured supplies at a small clinical scale facility. In order to meet forecasts for projected commercial and clinical demand and to ensure uninterrupted supply for Keytruda®, a novel monoclonal antibody against PD-1, Merck commercialized two drug substance facilities in parallel. Through multiple interactions with the FDA, both facilities were licensed, one that was the initial clinical supply site, and, a second larger CMO site. The licensure of these two sites was based on a strong process and analytical comparability package. In this case study, the author will present the challenges and opportunities encountered via this multi-site strategy to supplying KEYTRUDA®. The focus will be on approaches taken towards late stage commercialization activities including process characterization and process performance qualification. The author will also highlight post approval activities that follow as a consequence of an accelerated CMC development timeline.