"Expedited Reviews: What you need to know to be Successful" – A case study

In the September issue, Frank Casty, MD, Senior Clinical Regulatory Advisor at NDA discussed "Expedited regulatory pathways and what you need to know to be successful." This month I am following up with a case study of Bavencio (avelumab) injection, a Biological License Application (BLA) that was able to come to market quickly by utilising the benefit of multiple expedited review pathways.

Bavencio is a drug indicated to treat an aggressive neuroendocrine tumour of the skin for which there are no other treatments. With fewer than 20,000 cases per year in the US, the drug qualified for Orphan Status and, like other rare diseases, the primary review for the treatment effect was based on a small patient population, in this case less than 88 patients.[1]

As the sponsor had a well-planned regulatory strategy and utilised all the tools available to them during the drug development process, they were able to obtain both the Fast Track and Breakthrough Therapy Designation (BTD). Based on BTD, a preliminary advice meeting was held with the FDA to discuss an Accelerated Approval approach. The sponsor benefitted from several multi-disciplinary meetings with FDA, an important advantage of requesting and receiving this designation early in the programme.

The BLA also utilised a Rolling Review Process with the nonclinical sections of the application submitted ahead of the clinical data. Finally, the FDA granted the company a Priority Review status which means the application was reviewed in a six-month time frame. All of this was accomplished without the need for an FDA Advisory Committee Meeting!

This case study is an excellent example of how a well-planned and meticulously executed regulatory strategy can lead to a collaborative and rapid review, approval and, most importantly, availability of a new treatment for patients in an area with high unmet medical need.

At NDA, we support many companies in both the US and Europe seeking multiple expedited review procedures.

Don't miss our webinar on "Leveraging Expedited Regulatory Pathways to Optimize Drug Development" where we discuss these strategies in more depth.

References:

1. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/761049Orig1s000TOC.cfm (Bavencio)

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