PRIME Experiences

EMA PRIME Workshop, 19th May 2017

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Opinions expressed are solely my own and do not express the views or opinions of Biogen

Background

Aducanumab is Biogen's investigational monoclonal antibody for patients with Alzheimer's Disease

- The potential for the inclusion of Aducanumab in the PRIME scheme was first considered by the company in 2015
- Application for inclusion in PRIME was prepared in advance of the formal launch of the scheme
  - Based on the adopted guideline 'Enhanced early dialogue to facilitate accelerated assessment of PRIority MEdicines (PRIME)'
  - Application for eligibility in accordance with annex 1

- ➢ Accepted as per guidance in May 2016
- ➢ Rapporteur assigned at June CHMP meeting
- ➢ Kick-off meeting in September 2016
  - EMA open to schedule very quickly

- Post-meeting EMA dialogue – extremely constructive
- Currently investigating optimal first formal engagement following PRIME scheme acceptance

Biogen's experiences so far

Kick-off meeting briefing package

- Tailored to key topics for future engagement
  - Tabulated assessment of topics for future discussion and stakeholders to be involved, including timelines
  - Substantial background to support key topics

Preparation for kick-off meeting

- Cannot stress enough the importance and value of dedicated EMA support/contact - many conversations on what to expect for the kick-off meeting and how best to prepare
- Approached the meeting from a multidisciplinary perspective as all aspects of a development program are key to the potential success of an accelerated process

Importance of the agenda (received ~1 week prior to meeting)

- Agenda was structured with specific points raised by the Rapporteur for consideration
- Slide deck to be structured according to the agenda
- Change to normal preparation for EMA meeting – no expectation to get into scientific detail!

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Biogen's experiences so far

Kick-off meeting with EMA, Rapporteur and CHMP/SAWP Chairs in September

- Rapporteur assessment team fully prepared and engaged
- Context for discussion and feedback was to facilitate a smooth regulatory pathway
- Clear that future scientific advice should be through centralised EMA advice and significant value in multi-stakeholder scientific advice
- EMA proposed to utilise shorter lead in time advice (40 days rather than 70) - in a 5-6 month procedure this is an advantage!
- Post-authorisation plans are key
- Recognition of need for HTAB engagement

Key outcomes

EMA agreement on future engagement

- Aim for 40 day SA procedure and potential prioritisation
- EMA request to get on the books ASAP for scientific advice due to very busy schedule

Post meeting discussion with EMA: If contemplating parallel SA (PSA) consider the full 70 day procedure due to complexity of discussions and allowing HTABs to become completely familiar with data/strategy

Post authorisation strategy is key for EMA – reassurance around unanswered questions to be addressed and supportive of MAA submission strategy

If considering PSA, clear need for HTAB advocacy prior to first procedure – potential advocacy/scoping document in advance of centralised Letter of Intent (LoI) step

Further discussion with patient advocacy groups to ensure best involvement

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Potential improvements

- Clear from the kick-off meeting that one of the Rapporteurs roles is to discuss the development program with the applicant and identify which areas/concerns should be raised to centralised advice
  - Important to also maintain the option of informal discussions on an ongoing basis

- Although centralised advice is preferred by the EMA, national SA can continue to be sought but may not always be possible
  - This should be made clear to potential applicants if this is the case
  - We believe it is important that national expertise in specific areas be included in future engagement, including that which has been previously sought

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Potential improvements

- Periodic update meetings with EMA/Rapporteur to check-in on progress and any changes in the development of each product – especially important when earlier in development and engagement may be less frequent

- Guidance on application and kick-off meeting clear and relatively straightforward to follow;
  - the briefing package for the kick-off meeting - on the one hand the guidance advises a short and focused package but the list of topics to cover in the annex is very long and requires substantial detail!

Thank you