13 February 2023

Dear Ataxia UK,

Thank you for your request to receive updates on the progress of SKYCLARYS® (omaveloxolone). We are writing with the news that the European Commission (EC) has authorised omaveloxolone for the treatment of Friedreich's ataxia (FA) in adults and adolescents aged 16 years and older.[1]

The EC's decision means omaveloxolone is approved across all 27 European Union member states, as well as Iceland, Liechtenstein, Norway and Northern Ireland (in line with Ireland). Biogen will be engaging with local reimbursement authorities in these countries with the goal of securing reimbursed access for appropriate patients. For Northern Ireland, the relevant reimbursement body is NICE.

Following Brexit, marketing authorisations for medicines in Great Britain (England, Scotland and Wales) are determined by the Medicines and Healthcare products Regulatory Agency (MHRA). There are a number of regulatory routes available to us with the MHRA which we are considering. This includes an independent filing or using a new regulatory pathway called the International Recognition Procedure (IRP) which takes into account the expertise and decision-making of trusted regulatory partners such as the EMA or U.S. Food and Drug Administration (FDA).

Biogen is considering these filing pathways in conjunction with preparing a robust submission to NICE and the Scottish Medicines Consortium (SMC). It is important to understand that in the UK, including Northern Ireland, a regulatory approval does not mean that patients can be prescribed a medicine by the NHS.[2] NICE and SMC are the decision-making bodies which determine whether a medicine is both clinically and cost-effective for patients. We are in dialogue with the MHRA, NICE and SMC on the process and timeline for our application for omaveloxolone.

We remain appreciative of the work done by the FA community to support those living with the condition.

Best wishes,

Jessica March
Associate Director for Public Policy & Government Affairs
Biogen UK & Ireland

[1] European Medicines Agency, Skyclarys (omaveloxolone), Union Register of medicinal products for human use, February 12th. Available from: https://ec.europa.eu/health/documents/community-register/html/h1786.htm
[2] The NHS Constitution for England. Available at: https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england. Accessed December 2023