

Dalzanemdor (SAGE-718) Awarded Innovation Passport Designation for Cognitive Impairment Associated with Huntington's Disease and Entry into the Innovative Licensing and Access Pathway by the U.K. Medicines and Healthcare products Regulatory Agency (MHRA)

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The U.K. Medicines and Healthcare products Regulatory Agency (MHRA) launched the Innovative Licensing and Access Pathway (ILAP) with the goal to accelerate the development and time to market for medicines. The ILAP Steering Group awarded an Innovative Passport Designation to dalzanemdor (SAGE-718) for cognitive impairment associated with Huntington's Disease (HD).

Dalzanemdor (SAGE-718) is an investigational NMDA receptor positive allosteric modulator (PAM) being studied as a potential treatment for cognitive impairment associated with certain neurodegenerative diseases, including HD.

Innovation Passport Designation supports enhanced coordination of development activities, including access to a range of development tools and other potential benefits. Eligibility for the designation is based on a set of criteria including the potential to treat a life-threatening or serious condition for which there is significant unmet need. ILAP does not necessarily lead to a faster development pathway or regulatory review process, and does not increase the likelihood of regulatory approval. More information can be found on the ILAP website.