First UK Patient Enrolled into Luminousâ„¢ Programme â€“ Novartis' 30,000 Patient Observational Study in Ophthalmology

RealWire

Luminous, launched today, will provide long-term effectiveness, safety, and patient reported outcome data on Lucentis® (ranibizumab) in 30,000 patients in real-life settings across the world

Frimley, August 22 2011 - Novartis Pharmaceuticals UK Ltd (Novartis) has announced the enrollment of the first UK patient into the Luminous™ programme, which aims to advance the understanding of retinal vascular diseases which cause vision loss, including wet Age-related Macular Degeneration (AMD), visual impairment due to Diabetic Macular Oedema (DMO) and visual impairment due to macular oedema secondary to Retinal Vein Occlusion (RVO). It also aims to evaluate the long-term effectiveness and safety of Lucentis® (ranibizumab) in clinical practice across large populations, in order to further enhance patient outcomes.

Luminous will collect prospective data from 30,000 patients across the globe attending ophthalmology clinics. The programme will also serve as a platform for pooling data from existing ranibizumab registries in several countries, including the UK. The design of the Luminous programme was developed by Novartis in consultation with leaders in the ophthalmology community and representatives from patient organisations, such as the AMD Alliance International.

“AMD Alliance International places patient safety as our main priority, and we expect the most robust level of drug safety monitoring for our members,” said Narinder Sharma, AMD Alliance. “We were happy to work with the broader ophthalmology community to shape the Luminous programme with this goal in mind.”

As part of the Luminous programme, physicians will be provided with instant visualisation of patient outcomes, and a real-time data analysis and comparison system to analyse patient data in their own practice compared with practices in the same country or worldwide.

Christopher Brand, Consultant Ophthalmologist at the Royal Hallamshire Hospital, Sheffield, is leading the enrollment of the first UK patient and explains what the programme means for patient care: “This programme will enable us to facilitate real-time comparisons between the results seen in the UK with different ranibizumab treatment regimens in clinics around the world. The information we receive could help us provide better care for our patients and identify the best course of therapy for each individual.”

Dr. Timothy Cave, Chief Scientific Officer at Novartis Pharmaceuticals UK Ltd

provides further details on the importance of the programme: “A wealth of data is already available on the safety and efficacy of ranibizumab from clinical trials, but we hope Luminous will further support this data and provide information on the long-term outcomes in clinical practice. Novartis is committed to ophthalmology and improving understanding and treatment of vascular diseases.”

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About Luminous
Luminous is a five-year observational, international, multicenter programme that will provide long-term effectiveness and safety data for ranibizumab as well as assess the treatment patterns and health related quality of life issues of patients treated with ranibizumab. The goal is to recruit more than 30,000 patients from outpatient ophthalmology clinics in countries where Novartis markets ranibizumab, including Australia, Canada and select countries in Asia, Europe and South America, to create one of the largest ophthalmology observational studies in the world. The Luminous Steering Committee (LSC), an external advisory board made up of medical experts, representatives from patient organisations and other experts, will provide guidance and interpretation of the data as it is collected. As an observational study, Luminous will not direct therapy or recommend any specific therapy.

About Lucentis (ranibizumab)
Ranibizumab is an anti-vascular endothelial growth factor (anti-VEGF) licensed for the treatment of Retinal Vein Occlusion (RVO) (central and branch), visual impairment due to Diabetic Macular Oedema (DMO) and wet Age Related Macular Degeneration (AMD). The National Institute for Health and Clinical Excellence (NICE) approved Lucentis for the treatment of wet AMD in 2008.

About Novartis
Novartis provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. Novartis is the only company with leading positions in these areas. In 2010, the Group’s continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges), (16 percent of net sales), were invested in R&D throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 121,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com [1].

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