





YOU ARE CORDIALLY INVITED TO ATTEND LEQVIO LAUNCH EVENT





FRIDAY, 22ND OF OCTOBER





HYBRID EVENT

Disclaimer:

Registration is only for cardiologist, GP, IM, Endocrinologist, FM, pharmacist, and nurses



CHAIRMEN



Prof. Khalid Al Habib

Professor of Cardiology, Interventional Cardiologist College of medicine, Department of Cardiac Sciences Treasurer of Saudi Heart Association King Fahad Cardiac Center at King Saud University Riyadh, Saudi Arabia





Consultant Interventional Cardiology, Director of KFMMC Cardiac Center. King Fahd Military Medical Complex, Dhahran, KSA



Prof. Mohamed Arafa

Professor of Cardiac Sciences, Senior Consultant Interventional Cardiology, King Fahd Cardiac Center, King Saud University. Consultant, Dallah Cardiac Center, Riyadh, KSA



Prof. Kamal Alghaleni

Professor, cardiology consultant. Vice Dean for Clinical Affairs. Director non invasive cardiology lab. King abdulaziz University Hospital.Jeddah







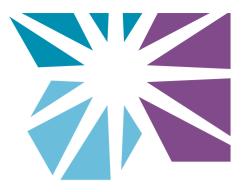
SPEAKERS



Dr. Osama Braiwish
President and CPO head Novartis Saudi.



Prof. Khalid Al Habib





Prof. Brian Ference

Professor and Director of Research in Translational Therapeutics Executive Director, Centre for Naturally Randomized Trials Strangways Research Laboratory University of Cambridge





Prof. Kausik Ray

Professor of Public Health and Consultant Cardiologist Director of the Imperial Centre for Cardiovascular Disease Prevention, Deputy Director of the Imperial Clinical Trials Unit and Head of Commercial Trials, Imperial College London





Prof. Walter Stefan Speidl

interventional cardiologist and intensivist at the Medical University of Vienna in Austria.









Legvio

Important note: This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. Presentation: Each pre filled syringe contains inclisiran sodium equivalent to 284 mg inclisiran in 1.5 ml solution. Each ml contains inclisiran sodium equivalent to 189 mg inclisiran, Indications: Legyio is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non familial) or mixed dyslipidaemia, as an adjunct to diet: • in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL C goals with the maximum tolerated dose of a statin, or alone or in combination with other lipid lowering therapies in patients who are statin intolerant, or for whom a statin is contraindicated. Dosage and administration: The recommended dose is 284 mg inclisiran administered as a single subcutaneous injection; initially, again at 3 months, followed by every 6 months, Missed doses: If a planned dose is missed by less than 3 months, inclisiran should be administered and dosing continued according to the patient's original schedule, If a planned dose is missed by more than 3 months, a new dosing schedule should be started - inclisiran should be administered initially, again at 3 months, followed by every 6 months, Treatment transition from monoclonal antibody PCSK9 inhibitors, Inclisiran can be administered immediately after the last dose of a monoclonal antibody PCSK9 inhibitor. To maintain LDL C lowering it is recommended that inclisiran is administered within 2 weeks after the last dose of a monoclonal antibody PCSK9 inhibitor. Special populations: Elderly (age >65 years) No dose adjustment is necessary in elderly patients. Hepatic impairment: No dose adjustments are necessary for patients with mild (Child Pugh class A) or moderate (Child Pugh class B) hepatic impairment. No data are available in patients with severe hepatic impairment (Child Pugh class C), Inclisiran should be used with caution in patients with severe hepatic impairment. Renal impairment: No dose adjustments are necessary for patients with mild, moderate or severe renal impairment or patients with end stage renal disease. There is limited experience with inclisiran in patients with severe renal impairment. Inclisiran should be used with caution in these patients. Paediatric population The safety and efficacy of inclisiran in children aged less than 18 years have not yet been established. No data are available, Method of administration: Subcutaneous use, Inclisiran is for subcutaneous injection into the abdomen; alternative injection sites include the upper arm or thigh. Injections should not be given into areas of active skin disease or injury such as sunburns, skin rashes, inflammation or skin infections. Each 284 mg dose is administered using a single pre filled syringe. Each pre filled syringe is for single use only. Inclisiran is intended for administration by a healthcare professional. Contraindications: Hypersensitivity to the active substance or to any of the excipients. Warnings and precautions: Haemodialysis; The effect of haemodialysis on inclisiran pharmacokinetics has not been studied. Considering that inclisiran is eliminated renally, haemodialysis should not be performed for at least 72 hours after inclisiran dosing, Sodium content. This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium free". Fertility, Pregnancy and lactation: Pregnancy, There are no or limited amount of data from the use of inclisiran in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of inclisiran during pregnancy. Breast feeding: It is unknown whether inclisiran is excreted in human milk. Available pharmacodynamic/toxicological data in animals have shown excretion of inclisiran in milk. A risk to newborns/infants cannot be excluded. A decision must be made whether to discontinue breast feeding or to discontinue/abstain from inclisiran therapy, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman, Fertility: No data on the effect of inclisiran on human fertility are available. Animal studies did not show any effects on fertility. Adverse drug reactions: •Very common (≥1/10): •Common (≥1/100): •Co reactions at the injection site occurred in 8.2% and 1.8% of inclisiran and placebo patients, respectively, in the pivotal studies. The proportion of patients in each group who discontinued treatment due to adverse reactions at the injection site was 0.2% and 0.0%, respectively. All of these adverse reactions were mild or moderate in severity, transient and resolved without seguelae. The most frequently occurring adverse reactions at the injection site in patients treated with inclisiran were injection site reaction (3.1%), injection site pain (2.2%), injection site erythema (1.6%), and injection site rash (0.7%), Uncommon (>1/1.000 to <1/100); Interactions; Inclisiran is not expected to have clinically significant interactions with other medicinal products. Based on the limited data available, clinically meaningful interactions with atorvastatin, rosuvastatin or other statins are not expected.

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