INVITATION

We are delighted to invite you to a meeting for healthcare professionals

Friday 22nd & Saturday 23rd September 2017

Sheraton Hotel, Athlone

Gleeson Street, Co. Westmeath, Athlone

www.sheratonathlonehotel.com

AGENDA Friday 22nd & Saturday 23rd September

TIME	SUBJECT	PRESENTER
Friday 22nd September		
18:00	Registration, Tea & Coffee on Arrival	
18:30	'The Psychology of Bouncibility – How to build resilience within ourselves'	Shane Martin, Clinical Psychologist (Psychological Society of Ireland)
20:30	Dinner	
Saturday 23rd September		
09:30	'End of Life Treatment Considerations'	Dr. Catherine Wall, Consultant Nephrologist, Adelaide and Meath Hospital, Tallaght, Dublin 24.
10:15	'Patient Entitlements in Renal Care'	Ms. Eileen McBrearty, Renal Patient Care Coordinator, Beaumont Hospital, Dublin 9.
10:45	Tea & Coffee Break	
11:15	'Innovation in Renal Care'	Dr. Aisling O'Riordan, Consultant Renal Physician, Mater Misericordiae Hospital, Dublin 7.
12:00	*'Don't Give Up Your Knitting!*- The Art of Patient Engagement'	Ms. Bernie Carter, Assistant Director of Nursing
12:45	Lunch	

If you wish to attend this meeting, please confirm your registration and any special dietary requirements by emailing Roger Towey at rtowey@amgen.com or Fionan King at fionank@amgen.com

Aranesp® (darbepoetin alfa) and Aranesp® SureClick™ (darbepoetin alfa) Brief Prescribing Information

Please refer to the Summary of Product Characteristics (SPC) before prescribing Aranesp or Aranesp SureClick™. **Pharmaceutical Form:** Aranesp solution for injection presented in pre-filled syringes **(with or without automatic needle guard)** containing 10, 15, 20, 30, 40, 50, 60, 80, 100 and 150 micrograms darbepoetin alfa for single dose use only; Aranesp SureClick™ solution for injection presented in pre-filled pens containing 20, 40, 60, 80, 100 and 150 micrograms darbepoetin alfa for single dose use only. **Indication:** Treatment of symptomatic anaemia associated with chronic renal failure (CRF) in adults and paediatric patients. **Dosage and Administration:** Aranesp pre-filled syringes can be administered either subcutaneously (SC) or intravenously (IV). When changing the route of administration the same dose must be used and the haemoglobin monitored every one or two weeks. Aranesp SureClick™ should be administered SC only. Allow the pre-filled syringe/pen to reach room temperature before injecting. Aranesp should be administered in order to increase haemoglobin to not greater than 12 g/dl (7.5 mmol/l), with a target range of 10 g/dl (6.2 mmol/l) to 12 g/dl (7.5 mmol/l). SC use is preferable in patients not receiving haemodialysis to avoid the puncture of peripheral veins. A rise in haemoglobin of greater than 2.0 g/dl (1.25 mmol/l) over a four week period should be avoided. ***Correction Phase for adults and paediatric patients ≥ 11 years of age:*** Initial dose by SC or IV administration is 0.45 μg/kg body weight as a single injection once weekly. Alternatively, in patients not on dialysis, the following initial doses can also be administered SC as a single injection: of 0.75 μg/kg once every two weeks or 1.5 μg/kg once monthly. The 1.5 μg/kg once monthly dose should only be given to adults. Correction of anaemia in paediatric patients with once monthly Aranesp dosing frequency has not been studied. If the increase in haemoglobin is inadequate (less than 1 g/dl (0.6 mmol/l) in four weeks) increase the dose by approximately 25%. Dose increases must not be made more frequently than once every four weeks. If the rise in haemoglobin is greater than 2.0 g/dl (1.25 mmol/l) in four weeks reduce the dose by approximately 25%. If the haemoglobin exceeds 12 g/dl (7.5 mmol/l), a dose reduction should be considered. Measure haemoglobin every one or two weeks until stable, thereafter haemoglobin can be measured at longer intervals. No guidance regarding the correction of haemoglobin is available for paediatric patients 1 to 10 years of age. Treatment of paediatric patients younger than 1 year of age has not been studied. ***Maintenance Phase for adults and paediatric patients ≥ 11 years of age:*** In dialysis patients continue to administer Aranesp as a single injection once weekly or once every two weeks. Dialysis patients converting from weekly to fortnightly dosing should initially receive a dose equivalent to twice the weekly dose. In patients not on dialysis, Aranesp may continue to be administered as a single injection once weekly or once every two weeks or once monthly. For patients treated with Aranesp once every two weeks, after the target haemoglobin has been achieved Aranesp may then be administered SC once monthly using an initial dose of twice the previous fortnightly dose. Any further required dose adjustments should be done in approximately 25% increments. If haemoglobin exceeds 12 g/dl (7.5 mmol/l), a dose reduction should be considered. Patients should be monitored closely to ensure the lowest approved dose of Aranesp is used to provide adequate control of the symptoms of anaemia. After any dose or schedule adjustment, monitor haemoglobin every one or two weeks. Dose changes in the maintenance phase should not be made more frequently than every two weeks. Please refer to the SPC for further information on the management of haemoglobin levels. ***r-HuEPO conversion specific to adults and paediatric patients ≥ 11 years of age:*** Patients receiving r-HuEPO may change to ARANESP. Please refer to the SPC for details on dose calculations. **Contra-indications:** Poorly controlled hypertension. Hypersensitivity to the active substance or excipients. **Special Warnings and Precautions:** Monitor blood pressure in all patients, particularly when initiating Aranesp therapy. Cases of severe hypertension, including hypertensive crisis, hypertensive encephalopathy and seizures have been observed in CRF patients treated with Aranesp. Evaluate iron status prior to and during treatment supplementary iron therapy may be necessary; non-response to therapy with Aranesp should be investigated. To improve the traceability of erythropoiesis-stimulating agents (ESAs), the trade name of the administered ESA should be clearly recorded in the patient file. Pure red cell aplasia caused by neutralising anti-erythropoietin antibodies has been reported in association with ESAs, including Aranesp. This has been predominantly reported in patients with CRF treated subcutaneously. These antibodies have been shown to cross-react with all erythropoietic proteins, and patients suspected or confirmed to have neutralising antibodies to erythropoietin should not be switched to Aranesp. A paradoxical decrease in haemoglobin and development

of severe anaemia associated with low reticulocyte counts should prompt to discontinue treatment with epoetin and perform anti-erythropoietin antibody testing. Aranesp should be used with caution in patients with liver disease, sickle cell anaemia or epilepsy. The needle cover of the pre-filled syringe contains dry natural rubber (a derivative of latex) which may cause allergic reactions. In clinical studies an increased risk of death, serious cardiovascular events or cerebrovascular events including stroke and vascular access thrombosis were observed when ESAs were administered to target a haemoglobin of greater than 12 g/dl (7.5 mmol/l). Serum potassium levels should be monitored regularly during Aranesp therapy; if an elevated or rising potassium level is observed consider ceasing Aranesp administration until potassium level is corrected. This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'. **Interactions:** If darbepoetin alfa is given concomitantly with substances that are highly bound to red blood cells e.g. cyclosporin or tacrolimus, monitor blood levels of these drugs and adjust the dose as the haemoglobin rises. **Pregnancy and lactation:** There are no adequate and well controlled studies in pregnant women. Exercise caution when prescribing Aranesp to pregnant women. It is unknown whether Aranesp is excreted in human milk. A decision must be made whether to discontinue breast-feeding or to discontinue from Aranesp. **Undesirable Effects:** Incidence of adverse reactions from controlled clinical studies and post-marketing experience are: very common (≥1/10), hypertension and hypersensitivity (serious hypersensitivity reactions including anaphylactic reaction, angioedema, allergic bronchospasm, skin rash and urticaria); common (≥1/100 to <1/10) stroke, rash/erythema, injection site pain; uncommon (≥1/1000 to <1/100) convulsions, thromboembolic events; unknown incidence pure red cell aplasia. Please consult the SPC for a full description of undesirable effects. **Pharmaceutical Precautions:** Aranesp must not be mixed or administered as an infusion with other medicinal products. Store in a refrigerator at 2°C to 8°C. Do not freeze. Keep container in outer carton to protect from light. For ambulatory use, Aranesp may be removed from storage once for a maximum single period of 7 days at room temperature (up to 25°C). Once a syringe, or pre-filled pen has been removed from the refrigerator and has reached room temperature (up to 25° C) it must either be used within 7 days or disposed of. **Legal Category:** POM.

Presentation and Marketing Authorisation Numbers:

Aranesp 10 μg/0.4ml: Pack of 4: EU/1/01/185/002
Aranesp 15 μg/0.375ml: Pack of 4: EU/1/01/185/077*
Aranesp 20 μg/0.5ml: Pack of 4: EU/1/01/185/079*
Aranesp 30 μg/0.3ml: Pack of 4: EU/1/01/185/081*
Aranesp 40 μg/0.4ml: Pack of 4: EU/1/01/185/083*
Aranesp 50 μg/0.5ml: Pack of 4: EU/1/01/185/085*
Aranesp 60 μg/0.3ml: Pack of 4: EU/1/01/185/087*
Aranesp 80 μg/0.4ml: Pack of 4: EU/1/01/185/089*
Aranesp 100 μg/0.5ml: Pack of 4: EU/1/01/185/091*
Aranesp 150 μg/0.3ml: Pack of 4: EU/1/01/185/095*
Aranesp SureClick™ 20 μg/0.5ml: Pack of 1: EU/1/01/185/047
Aranesp SureClick™ 40 μg/0.4ml: Pack of 1: EU/1/01/185/049
Aranesp SureClick™ 60 μg/0.3ml: Pack of 1: EU/1/01/185/051
Aranesp SureClick™ 80 μg/0.4ml: Pack of 1: EU/1/01/185/052
Aranesp SureClick™ 100 μg/0.5ml: Pack of 1: EU/1/01/185/053
Aranesp SureClick™ 150 μg/0.3ml: Pack of 1: EU/1/01/185/054
*with automatic needle guard
Not all presentations may be marketed.

Prices in the Republic of Ireland are available on request.

Marketing Authorisation Holder: Amgen Europe B.V., Minervum 7061, NL-4817 ZK Breda, The Netherlands. Further information is available from Amgen Limited, 240 Cambridge Science Park, Milton Road, Cambridge, CB4 0WD. Aranesp is a registered trademark of Amgen Inc.

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Adverse events should be reported to Amgen Limited on +44 (0) 1223 436712.