

## Annex I Summary Of Product Characteristics

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### Annex I Summary Of Product

Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains 114 mcg of indacaterol (as acetate), 58 mcg of glycopyrronium bromide equivalent to 46 mcg of glycopyrronium and 136 mcg of mometasone furoate. Excipient(s) with known effect. Each capsule contains 25 mg of lactose monohydrate.

### ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS

ANNEX I. SUMMARY OF PRODUCT CHARACTERISTICS . 2 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. See section 4.8 for how to report adverse reactions.

### ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS

Onasemnogene abeparvovec is a gene therapy medicinal product that expresses the human survival motor neuron (SMN) protein. It is a non-replicating recombinant adeno-associated virus serotype 9 (AAV9) based vector containing the cDNA of the human SMN gene under the control of the cytomegalovirus enhancer/chicken- $\beta$ -actin-hybrid promoter.

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### ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS

corresponding Summary of Product Characteristics. Dosing schedule in combination with bortezomib, melphalan and prednisone (6-week cycle regimens): The recommended dose is DARZALEX 16mg/kg body weight administered as an intravenous infusion according to the following dosing schedule in Table 2.

### **ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS**

ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS . 2 1. NAME OF THE MEDICINAL PRODUCT Betaferon 250 microgram/ml, powder and solvent for solution for injection. 2. QUALITATIVE AND QUANTITATIVE COMPOSITION Recombinant interferon beta-1b\* 250 microgram (8.0 million IU) per ml when reconstituted.

### **ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS**

ANNEX I . SUMMARY OF PRODUCT CHARACTERISTICS . 2 1. NAME OF THE MEDICINAL PRODUCT . AVAMYS. 27.5 micrograms/spray, nasal spray suspension . 2. QUALITATIVE AND QUANTITATIVE COMPOSITION . Each spray actuation delivers 27.5 micrograms of fluticasone furoate. For the full list of excipients, see section 6.1.

### **ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS**

ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS . 2 1. NAME OF THE MEDICINAL PRODUCT Xyrem 500 mg/mL oral solution 2. QUALITATIVE AND QUANTITATIVE COMPOSITION Each mL of solution contains 500 mg of sodium oxybate. For the full list of excipients, see section 6.1. 3. PHARMACEUTICAL FORM

### **ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS**

ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS. 2 1. NAME OF THE MEDICINAL PRODUCT Januvia 25mg film-coated tablets 2. QUALITATIVE AND QUANTITATIVE COMPOSITION Each tablet contains sitagliptin phosphate monohydrate, equivalent to 25mg sitagliptin. For the full list of excipients, see section 6.1. 3. PHARMACEUTICAL FORM

### **ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS**

The finished product is composed of one or more infusion bags which contain a dispersion of  $1.2-20 \times 10^6$  cells/mL suspended in cryopreservative solution. Each infusion bag contains approximately 20 mL of Zynteglo. The quantitative information regarding strength, CD34+ cells, and dose for the medicinal product is

### **ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS**

ANNEX I . SUMMARY OF PRODUCT CHARACTERISTICS . 2 . 1. NAME OF THE MEDICINAL PRODUCT . Twinrix Adult, suspension for injection in pre-filled syringe . Hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed). 2. QUALITATIVE AND QUANTITATIVE COMPOSITION . 1 dose (1 ml) contains:

### **ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS**

ANNEX I . SUMMARY OF PRODUCT CHARACTERISTICS . 2 . 1. NAME OF THE MEDICINAL PRODUCT . Menveo powder and solution for solution for injection . Meningococcal Group A, C, W-135 and Y conjugate vaccine . 2. QUALITATIVE AND QUANTITATIVE COMPOSITION . One dose (0.5 ml of the reconstituted vaccine) contains:

### **ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS**

ANNEX I . SUMMARY OF PRODUCT CHARACTERISTICS . 2 . 1. NAME OF THE MEDICINAL PRODUCT . Rotarix powder and solvent for oral suspension . Rotavirus vaccine, live . 2. QUALITATIVE AND QUANTITATIVE COMPOSITION . After reconstitution, 1 dose (1 ml) contains:

### **ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS**

intramuscularly on Days 1, 15, 29, and once monthly thereafter. Please refer to the Summary of Product Characteristics of fulvestrant. Prior to the start of treatment with the combination of palbociclib plus fulvestrant, and throughout its duration, pre/perimenopausal women should be treated with LHRH agonists according to local clinical practice.

### **ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS**

1. NAME OF THE MEDICINAL PRODUCT MAVENCLAD 10 mg tablets 2. QUALITATIVE AND QUANTITATIVE COMPOSITION Each tablet contains 10 mg of cladribine. Excipients with known effect Each tablet contains 64 mg sorbitol. For the full list of excipients, see section 6.1. 3. PHARMACEUTICAL FORM Tablet.

### **ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS**

This medicinal product contains 2.5 mg benzyl alcohol per dose. chemical/physiological characteristics of interferon beta, suggests that levels of interferon beta-1a of the administered product should be clearly recorded.

### **ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS**

The veterinary medicinal product should be administered to piglets between 48 to 72 hours after birth with a single intramuscular injection of 20 mg toltrazuril/kg body weight and 100 mg iron (as gleptoferron complex)/kg body weight, which is a dose volume of 0.55 ml/kg body weight.

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