A phase III, randomized, double-blind, active, controlled, multinational, multicentre, non-inferiority trial using Carbetocin room temperature stable (RTS) for the prevention of postpartum haemorrhage during the third stage of labour in women delivering vaginally

### Current Project Brief

#### Objectives and Background

The objective of this trial is to evaluate if carbetocin RTS 100µg intramuscular (IM) is non-inferior to oxytocin 10 IU IM, as a uterotonic during the third stage of labour, in preventing postpartum haemorrhage in women delivering vaginally.

Postpartum haemorrhage (PPH) is the leading cause of maternal mortality in low-income countries and it contributes to nearly a quarter of maternal deaths globally. The majority of deaths due to PPH could be avoided through the use of prophylactic uterotonics during the third stage of labour and by timely and appropriate management. Oxytocin (IM/IV, 10 IU) is recommended as the uterotonic drug of choice. Based on the manufacturer’s recommendations, oxytocin should be stored under refrigeration. Carbetocin appears to be a promising agent in the prevention of PPH, is a more stable molecule and induces a prolonged uterine response, when administered postpartum. The manufacturer of carbetocin (Ferring Pharmaceuticals) has recently developed a room temperature stable formulation (carbetocin RTS) which makes it an attractive option for countries where maintaining the cold chain is problematic. Merck for Mothers, Ferring Pharmaceuticals and the World Health Organization would like to evaluate the room temperature stable carbetocin solution for injection as a promising intervention for reducing PPH particularly in settings where cold storage is difficult to achieve and maintain.

The trial is expected to finish recruitment on 30 January 2018.

#### Geographic location

Argentina, Egypt, India, Kenya, Nigeria, Singapore, South Africa, Thailand, Uganda, United Kingdom.

#### Main deliverables

Should this trial demonstrate that carbetocin RTS is non-inferior to oxytocin in preventing postpartum haemorrhage, in settings where the cold chain could not be guaranteed, oxytocin could be replaced by carbetocin RTS as the uterotonic used during the third stage of labour.

#### Partners

Merck for Mothers, Ferring Pharmaceuticals

#### Sources of funding

Merck for Mothers

#### Date Issued

January 2018