Merck Announces Findings from WHO-led Study of Investigational Heat-Stable Carbetocin for Preventing Excessive Bleeding After Childbirth

Release Date:
Wednesday, June 27, 2018 5:00 pm EDT

Terms:
Corporate News  Corporate Responsibility News  Latest News  #Merck  #MRK  $MRK  Merck  MRK  MSD

Dateline City:
KENILWORTH, N.J.

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, through its Merck for Mothers initiative announced study results on an investigational heat-stable formulation of carbetocin for the prevention of excessive bleeding after childbirth, also known as postpartum haemorrhage (PPH). The results demonstrated that heat-stable carbetocin is clinically non-inferior to the standard of care, oxytocin, for the primary outcome of ≥500 ml blood loss or additional uterotonic use. Non-inferiority was not demonstrated for the second primary outcome of blood loss of ≥1,000 ml or more.

Results from the CHAMPION (Carbetocin Haemorrhage Prevention) clinical trial, led by the World Health Organization (WHO) and conducted as part of a public-private collaboration with Ferring and Merck for Mothers, were published in the New England Journal of Medicine (NEJM). CHAMPION is the largest study conducted in PPH prevention, with nearly 30,000 women from 10 countries. The CHAMPION trial of investigational heat-stable carbetocin was conducted by the WHO Department of Reproductive Health and Research, including the UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), with scientific and financial support provided by Merck for Mothers.

The current standard of care for the prevention of PPH, oxytocin, is temperature sensitive. Multiple studies in low- and lower-middle-income countries have consistently revealed degradation and potential loss of efficacy of oxytocin, which could be due to inadequate storage and distribution. Because of its heat-stability, this investigational formulation of carbetocin has the potential to be used in low- and lower-middle income countries, where the refrigeration of medicines can be difficult to achieve and maintain.

Every year, 14 million mothers are affected by PPH. Although most deaths due to PPH are preventable, it contributes to the leading direct cause of maternal mortality worldwide, causing approximately 70,000 deaths every year.

“No woman should die giving life, and our mission is to give mothers around the world access to affordable, life-saving medical interventions,” said Julie L. Gerberding, Chief Patient Officer at Merck. “Prevention is key, which is why we are collaborating on the CHAMPION project. The collaboration has brought innovation developed in the private sector into the public sector in an effort to address unmet needs in countries where the majority of maternal deaths occur.”

The collaboration began when Merck for Mothers first approached Ferring and the WHO about studying the investigational heat-stable carbetocin in an effort to increase public sector access, given the organizations’ shared goals of PPH prevention. Ferring will now seek registrations and manufacture heat-stable carbetocin for low- and lower-middle income countries. The parties will work together with the aim of making heat-stable carbetocin available at an affordable and sustainable price for appropriate cases in the public sector of low- and lower-middle income countries that have a high burden of maternal mortality.

*The availability of heat-stable carbetocin is subject to regulatory review and approval in relevant countries.

About the CHAMPION trial

CHAMPION, (Carbetocin Haemorrhage Prevention), the world’s largest clinical trial in the prevention of PPH, was a double-blind, randomized, non-inferiority trial designed to compare the effectiveness and safety of investigational heat-stable carbetocin to oxytocin in the prevention of PPH after vaginal birth. The trial, conducted by the WHO Department of Reproductive Health and Research, including the UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), enrolled nearly 30,000 women in ten countries including Argentina, Egypt, India, Kenya, Nigeria, Singapore, South Africa, Thailand, Uganda and the UK. Heat-stable carbetocin was researched and developed by Ferring Pharmaceuticals and the CHAMPION trial was funded by Merck for Mothers.

Results demonstrated that heat-stable carbetocin is clinically non-inferior to oxytocin for the primary outcome of ≥500 ml blood loss or additional uterotonic use. The frequency of blood loss ≥500 ml or additional uterotonic use was 14.5% in the...
carbetocin group and 14.4% in the oxytocin group (Relative Risk (RR): 1.01, 95% confidence interval (CI): 0.95 to 1.06), consistent with non-inferiority.

Non-inferiority was not demonstrated for the second primary outcome of blood loss of ≥ 1,000 ml (1.51% carbetocin group vs 1.45% in the oxytocin group, RR: 1.04, CI: 0.87 to 1.25). However, the trial was underpowered for this outcome. There were no significant differences between groups in other measures of bleeding or in adverse effects.

**About Merck for Mothers**

Every day, approximately 830 women die from preventable causes related to pregnancy and childbirth. *Merck for Mothers* is a 10-year, $500 million initiative to create a world where no woman dies from complications of pregnancy and childbirth. Drawing on the company's history of discovering innovative, life-saving medicines and vaccines, *Merck for Mothers* is applying the company's scientific and business expertise – as well as its financial and human resources – to reduce maternal mortality around the world. Learn more at [www.merckformothers.com](http://www.merckformothers.com) and [@MerckforMothers](https://twitter.com/MerckforMothers).

**About Merck**

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit [www.merck.com](http://www.merck.com) and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.

**Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA**

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2017 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

**Language:**

English

**Contact:**

For Merck & Co., Inc.
Media:
Doris Li, 908-246-5701
or
Investors:
Teri Loxam, 908-740-1986
or
Michael DeCarbo, 908-740-1807

**Ticker Slug:**

*Ticker: MRK*  
*Exchange: NYSE*  
@merck