



Ferring Pharmaceuticals and MSD Announce Completion of Largest Clinical Trial Ever Conducted in Postpartum Haemorrhage

- *Excessive bleeding after childbirth (postpartum haemorrhage or PPH) is the leading direct cause of maternal mortality worldwide¹*
- *The CHAMPION trial is assessing the effectiveness and safety of heat-stable carbetocin vs. oxytocin, the current standard of care, for preventing PPH after vaginal birth^{2,3}*

Saint-Prex, Switzerland, & Kenilworth, N.J., February 22, 2018—Ferring Pharmaceuticals and MSD, known as Merck & Co., Inc., Kenilworth, N.J., U.S.A., through its *MSD for Mothers* initiative, today announced the completion of CHAMPION (**Carbetocin Haemorrhage Prevention**), a global clinical trial conducted by the Human Reproduction Program (HRP) at the World Health Organization (WHO). CHAMPION is investigating whether Ferring's proprietary and heat-stable carbetocin could offer a new solution to prevent excessive bleeding after childbirth (postpartum haemorrhage or PPH).^{2,3} Involving nearly 30,000 women in 10 countries, it is the largest clinical trial ever conducted in PPH.^{2,3}

1 out of 5 worldwide deaths during childbirth happen in India, new hope on the horizon now.

Globally, about 800 women die every day of preventable causes related to pregnancy and childbirth; 20 per cent of these women are from India,¹ and **Postpartum Haemorrhage (PPH) is the leading cause of maternal mortality in India³**

While one of India's millennium development goals (MDG) was to reduce its Maternal Mortality Ratio by three quarters, India did not reach this goal and its MMR stands at 167 and haemorrhages and infections still continue to be the leading causes.^{1,2}

This situation may now change, thanks to a large trial (*The CHAMPION trial*) undertaken by the Human Reproduction Program (HRP) at the World Health Organization enrolling nearly 30,000 women in 10 countries including **India, wherein the effectiveness and safety of heat-stable carbetocin vs. oxytocin, the current standard of care, for preventing PPH after vaginal birth was compared.**

The good news is that this trial is now complete and if the results are favourable, it will lead to the application for approval of this product by the concerned companies. Ferring Pharmaceuticals and MSD, known as Merck & Co., Inc., through its *MSD for Mothers* initiative, announced the completion of CHAMPION (**Carbetocin Haemorrhage Prevention**).

According to SRS 2001-2003, PPH (post-partum haemorrhage) for which the above-mentioned drug is used, accounts 38 percent of maternal deaths. PPH is a frequent complication of delivery and its reported incidence in India is 2% - 4% after vaginal delivery and 6% after cesarean section with uterine atony being the most common cause (50%).

Various studies in different regions of India report different prevalence of PPH^{4,5}.

- North east region: 21.27%
- Delhi: 22.7%
- Orissa: 28.57%
- Western India: 24.6%

Indian women are more prone to succumb during childbirth because of ethnicity, anemia, obesity, prolonged labour & lack of right medicine; and completion of this trial offers a ray of hope.

The CHAMPION trial compares the effectiveness and safety of Ferring's heat-stable carbetocin versus the current standard of care, oxytocin, for preventing PPH after vaginal birth.^{2,3} Heat-stable carbetocin could address a significant limitation associated with oxytocin – the need for refrigeration during shipping and storage to prevent degradation in temperatures above 8°C.^{3,4} Heat-stable carbetocin may remain active long-term in hot and humid climates,³ and could potentially reduce the incidence of PPH in areas where cold storage is difficult to achieve and maintain,³ **Error! Bookmark not defined.** and where 99% of maternal deaths due to PPH currently occur. **Error! Bookmark not defined.**

“Using our established expertise in Reproductive Medicine and Women’s Health, we strive to find innovative treatments that will help to dramatically reduce the number of mothers dying as a result of childbirth,” said Professor Klaus Dugi, Chief Medical Officer, Ferring Pharmaceuticals. “Our heat-stable carbetocin is just one example of this research effort and forms part of our ongoing commitment to safeguarding the health of families worldwide. We are looking forward to seeing the results from the CHAMPION trial and hope that the learnings will usher in a new era in the prevention of PPH.”

If the results of the CHAMPION trial are favourable, Ferring will seek registration of heat-stable carbetocin on a broad basis around the world. If approved, Ferring would manufacture the product and it would be provided to the public sector of low- and lower-middle-income countries at an affordable and sustainable access price. Results from the trial are expected to be presented and published during the second half of 2018.

“The CHAMPION trial has the potential to change the paradigm in how we save more mothers from dying during childbirth,” said Julie L. Gerberding, M.D., M.P.H. Executive Vice President & Chief Patient Officer, Strategic Communications, Global Public Policy and Population Health at MSD. “Along with our partners, we recognized that heat-stable carbetocin could be a transformative solution to preventing PPH, which is the number one cause of maternal mortality. Through MSD for Mothers, we provided our company’s scientific expertise and financial resources to prove the concept and ultimately make a sustainable impact on the health of mothers, families and communities.”

About the CHAMPION* trial^{2,3}

CHAMPION (Carbetocin Haemorrhage Prevention), the world’s largest clinical trial in postpartum haemorrhage, is being undertaken to compare the effectiveness and safety of heat-stable carbetocin to oxytocin in the prevention of postpartum haemorrhage after vaginal births. The trial conducted by the Human Reproduction Program (HRP) at the World Health Organization enrolled nearly 30,000 women in 10 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 *MSD for Mothers*.

About Ferring Pharmaceuticals:

Ferring Pharmaceuticals is a research-driven, specialty biopharmaceutical group committed to helping people around the world build families and live better lives. Headquartered in Saint-Prex, Switzerland, Ferring is a leader in reproductive medicine and women's health, and in specialty areas within gastroenterology and urology. Ferring has been developing treatments for mothers and babies for over 50 years. Today, over one third of the company's research and development investment goes towards finding innovative and personalised healthcare solutions to help mothers and babies, from conception to birth. Founded in 1950, Ferring now employs approximately 6,500 people worldwide, has its own operating subsidiaries in nearly 60 countries and markets its products in 110 countries.

Learn more at www.ferring.com and [@Ferring](#), or connect with us on [Facebook](#), [Instagram](#) and [LinkedIn](#).

About MSD for Mothers

Every day, approximately 830 women die from preventable causes related to pregnancy and childbirth.⁵ MSD 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, MSD 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 <http://www.msdformothers.com/> and [@MSDforMothers](#).

About MSD

For more than a century, MSD, a leading global biopharmaceutical company, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. MSD is a trade name of Merck & Co., Inc., with headquarters in Kenilworth, N.J., U.S.A. 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, MSD 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 <http://www.msd.com/> and connect with us on Twitter, LinkedIn and YouTube.

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. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. 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 2016 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)

Contact details:

Ferring Pharmaceuticals

BhavinVaid

Head of Corporate Communications

+41 58 301 0952 (direct)+41 79 191 0632 (mobile)

bhavin.vaid@ferring.com

Lindsey Rodger

Senior Manager, Corporate Communications

+41 58 451 4023 (direct)

+41 79 191 0486 (mobile)

lindsey.rodger@ferring.com

MSD for Mothers

Claire Gillespie, +1 267-305-0932

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