News Release

Media Contacts: Mary-Jo Barr (438) 340-8668
Lucy Hopkins (647) 462-7446

NEXPLANON® Contraceptive Arm Implant Now Available for Use in Canada

- NEXPLANON® is the first single-rod arm implant to be approved by Health Canada for the prevention of pregnancy.[1]
- The implant provides Canadians with a new birth control option that can be removed at any point during the three-year period by a healthcare professional.[1]

KIRKLAND, QC – September 24, 2020 - Merck Canada Inc., an affiliate of Merck & Co., Inc., known as MSD outside the United States and Canada, announced today that NEXPLANON® (etonogestrel implant) 68 mg, a hormonal contraceptive implant, is now available in Canada.[1] The implant, approved by Health Canada for the prevention of pregnancy for up to three years, provides Canadians with a progestin-only contraceptive option that is long-acting .[1]

“Health Canada’s approval of NEXPLANON® is an important contribution to the Canadian contraceptive landscape,” says Dr. Ashley Waddington, Family Planning specialist in the Department of Obstetrics and Gynecology, Queen’s University. “Access to this reversible contraceptive method is good news for those who cannot take contraceptives containing estrogen due to medical conditions or patient preference, or for whom intrauterine devices are contraindicated or not desired. More contraceptive options allow for more patient choice and ensures Canadians can achieve their family planning goals.”

The arm implant contains etonogestrel, a hormone that is continuously released in small amounts into the blood.[1] It prevents pregnancy in two ways: by stopping the release of egg cells from the ovaries and by causing changes in the cervical mucus to make it difficult for sperm to enter the uterus.[1]

“Merck Canada is excited to provide a new birth control option,” says AnnA Van Acker, President, Merck Canada. “This arm implant is an example of Merck’s commitment to offer a range of birth control options in our growing Women’s Health portfolio.”

Approximately the size of a matchstick, the implant is a small, soft and flexible plastic rod that is inserted by a healthcare professional just below the skin on the inner side of a patient’s upper arm.[1] When inserted correctly, NEXPLANON was shown to be effective, with less than one pregnancy per 100 patients who used the birth control implant for one year.[1]

About NEXPLANON®

NEXPLANON is approved for pregnancy prevention for up to three years.[1] By the end of the third year, the implant must be removed and may be replaced with a new implant, if continued contraceptive protection is desired.[1] It will not protect patients against sexually transmitted

infections (STIs), including HIV/AIDS.[1] To prevent STIs, patients should use latex or polyurethane condoms while using the implant.[1]

The arm implant is radiopaque, meaning physicians can verify presence of the implant after insertion and can locate it prior to removal using two-dimensional X-ray, computed tomography (CT scan) and ultrasound scanning (USS), or magnetic resonance imaging (MRI).[1] After insertion and prior to removal, physicians should be able to verify the presence of the implant in the patient's arm by palpation.[1] If the implant cannot be palpated, the physician can use one of the four available methods to verify presence of the implant.[1] Until the presence of the implant can be verified, patients should be advised to use a non-hormonal contraceptive method, such as condoms.[1]

The approval of the implant is based on results from a multicenter, randomized, double-blind, parallel group bioequivalence study comparing the radiopaque implant to the non-radiopaque etonogestrel subdermal implant (IMPLANON®).[1] NEXPLANON and the non-radiopaque etonogestrel subdermal implant met comparative bioavailability standards with respect to rate and extent of absorption of etonogestrel.[1] The safety and efficacy of the non-radiopaque implant as a birth control option was demonstrated in adults who were between the ages of 18 and 40 years at the beginning of the clinical trial.[1]

The clinical trials, which were up to three years in duration, involved 923 subjects, with 1756 woman-years of use with the non-radiopaque etonogestrel implant (IMPLANON). In a subgroup of patients aged 18-35, six pregnancies were reported, resulting in a Pearl Index of 0.38.[1] Each conception was likely to have occurred shortly before or within two weeks following removal of the non-radiopaque etonogestrel implant.[1] Pregnancies were observed to occur as early as seven to 14 days after removal of the arm implant.[1] If pregnancy is not desired after removal of the implant, another method of birth control must be started immediately.[1]

About Merck

For more than 125 years, Merck, 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 in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. For more information about our operations in Canada, visit www.merck.ca and connect with us on YouTube and Twitter @MerckCanada

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).

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Please see the product monograph for NEXPLANON® (etonogestrel implant) at:

https://www.merck.ca/static/pdf/NEXPLANON-PM_E.pdf

References

[1] NEXPLANON® Product Monograph. Merck & Co. Inc. Updated May 25, 2020.