This document is intended to provide information to an international audience outside the USA and the UK.

International press release

June 2013

Exelgyn launch their misoprostol indicated in medical termination of pregnancy up to 49 days of amenorrhea.

A big step towards safety and compliance for patients and health care professionals …

In August 2013, Exelgyn will launch via their European distributor network their own misoprostol under two different trade names: **MisoOne®** and **Topogyne®**. The product is an oral 400 mcg misoprostol tablet, approved in medical termination of developing intra-uterine pregnancy, in sequential use with mifepristone (Mifegyne®), up to 49 days of amenorrhea. Exelgyn, aims to provide safe and reliable treatments in gynecology and this new product is in accordance with practice and current guidelines.

Following a global review of the literature and expert opinions, and following safety and efficacy concerns regarding the protocols used, the European Medicines Agency (EMA) concluded in 2007 that the available data support the effectiveness of a 600 mg dose of mifepristone up to 63 days of amenorrhea. It confirmed as well, that the benefit/risk profile of **mifepristone 600 mg in combination with oral misoprostol 400 µg** for pregnancies up to 49 days of amenorrhea is favorable. Following this European arbitration, the Health Authorities of some countries decided to review their national guidelines.

Véronique Rebours-Mory, Managing Director of Exelgyn:

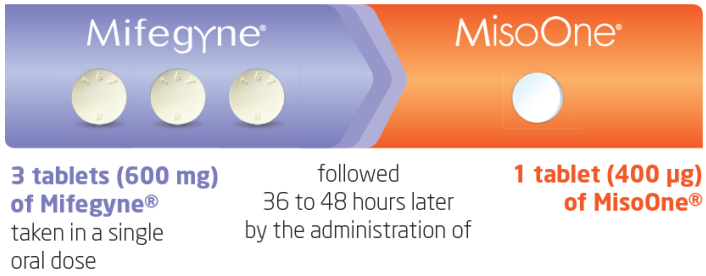
"With a 25 year experience in Woman Health Care and Termination of Pregnancy, Exelgyn's priority is to give access to health care professionals to safe and reliable treatments, but even more important to up to date and accurate information on the products and the benefit/risk balance. In 2010, we initiated the development of this new 400 mcg misoprostol and we are proud to make it available all over Europe in the coming months. Exelgyn has earned a reputation as a company that is active in promoting women's health, with high quality medicine and reliable supply and we tend to put our treatments available for women all over the world".

The product launch starts in the United Kingdom and will continue in several other European countries. MisoOne®/ Topogyne® is the first misoprostol tailored and approved for medical termination of pregnancy in 21 European countries.

About MisoOne®/ Topogyne®

MisoOne® (misoprostol 400 mcg) is a prostaglandin analogue indicated in medical termination of developing intra-uterine pregnancy, in sequential use with mifepristone (Mifegyne®), up to 49 days of amenorrhea. MisoOne® completed a European Decentralized Procedure in October 2012 in 21 European countries. The Marketing Authorizations are granted with the trade names: MisoOne®/ Topogyne®.

With MisoOne® used in combination with Mifegyne®, Exelgyn provides the complete method recommended by the EMA to medically terminate pregnancy up to 49 days of amenorrhea.



About Mifegyne®

Mifegyne® (mifepristone, RU486) is the first anti-progesterone molecule authorised for use in obstetrics and gynaecology.

In 1988, the first MA was obtained in France for medical termination of pregnancy up to 49 days of amenorrhea in combination with prostaglandin analogues.

Today, Mifegyne® is marketed in more than 30 countries worldwide.

Mifegyne® is an oral active anti-progesterone that acts by competing with endogenous progesterone for receptor binding sites.

Mifegyne® is approved in Europe in 4 indications:

- Medical termination of developing intra-uterine pregnancy in association with prostaglandin up to 63 Days of amenorrhea,

- Softening and dilatation of the *cervix uteri* prior to surgical termination of pregnancy during the first trimester,
- Preparation for the action of prostaglandin analogues in the termination of pregnancy for medical reasons (beyond the first trimester),
- Labour induction in foetal death *in utero*.

For more information on MisoOne® / Topogyne® or Mifegyne® please consult the Summary of the Product Characteristics:

MisoOne®: SmPC
Mifegyne®: SmPC

About Exelgyn

Dr. Sakiz established the company EXELGYN in France to ensure the continued production, distribution and research and development of Mifegyne® worldwide. The product was registered on the WHO's list of essential medicines in 2005.

The company is known as a pioneer in development and commercialization of the first Selective Progesterone Receptor Modulator (SPRM) in gynecology. Exelgyn joined the Nordic Group in 2010 in their ongoing drive for excellence. Exelgyn strives to improve women's healthcare and wellness by expanding access to safe and qualitative drugs worldwide. Exelgyn is involved and dedicated to provide distinctive products in therapeutics areas which require broad knowledge and expertise. Exelgyn embraces innovation and quality standards to make a difference in women lives.

If you have any questions, please feel free to contact:

Exelgyn SAS
254 Boulevard Saint- Germain – 75007 Paris - France
Phone: +33 173 001 640
Fax: +33 173 001 649
info@exelgyn.com
www.exelgyn.com