UPDATE: Safety and Efficacy of the IUB™ SCu300B MIDI Following Widespread Use

August 2017

Background
Over 40% of worldwide pregnancies each year are unintended, exposing women to major health risks and posing considerable economic burden to society. Women today have increased options and access to birth control means yet the availability of these methods do not always meet their needs, as is evident by the high discontinuation rates. Data from the US Centers for Disease Control and Prevention (CDC) shows that many women try at least five different kinds of birth control and are unhappy with them, suggesting alternative methods are in need.

Long acting reversible contraceptives (LARCs) have become in recent years a focus class in the search for such alternative products. The most prevalent type of LARC is the intrauterine device (IUD), the most effective reversible method of contraception, superior to other types of birth control in safety, cost-effectiveness and continuation rates.

Introduction
The IUB™ SCu300B MIDI (branded as Ballerine™ in certain territories) is a novel, hormone-free intrauterine contraceptive product approved for marketing since December 2014. Upon insertion in the uterus, the IUB™ coils into an elastic three-dimensional spherical form, conforming to the shape of the uterine cavity. The data presented herein was accumulated through ongoing post marketing surveillance, conducted by the manufacturer (OCON Medical Ltd., Israel) to monitor performance and evaluate the product’s safety and efficacy during widespread global use.

Materials and Methods
A total of 38,662 products were introduced to the market in Austria, Switzerland, Germany, Spain, Israel, Belgium, Slovakia and Hungary between February 2015 and June 2017. A database of adverse reactions was obtained during the period and up to the date of this report for a total of 27 months through ongoing vigilance reporting.

Results
Based on the pharmacovigilance data a total of 618 expulsions were reported resulting in an overall expulsion rate of 1.6%. 42 pregnancies, including one ectopic were reported for a 99.89% contraceptive efficacy rate. A total of 11 perforations occurred during the period representing a perforation rate of 1:3,514. Reports of pain or severe bleeding accounted for under 0.1%. There were no product-related reportable severe adverse events.

Discussion
Published data on IUDs reveals an overall expulsion rate of 6-10.2%, pregnancy rate of 1% and perforation rate of 1:909. The presented real-life data via pharmacovigilance reporting demonstrates that the IUB™ SCu300B MIDI provides reduced risks of expulsion and perforation compared to published data, along with elimination of malposition. Owing to the similar mode of action, contraceptive efficacy is high, meeting published efficacy rates of other IUDs.

Conclusions
In the population herein analyzed, the IUB™ SCu300B MIDI appears to provide a favorable safety profile and similar efficacy to standard IUDs. Current results remain consistent with those analyzed in an earlier report (WP171 of January 2017). To further substantiate efficacy, safety, bleeding profile as well as satisfaction and continuation measures, post marketing studies of the product have been initiated with results anticipated in early 2018.

1 Gilda Sedgh et al. of the Guttmacher Institute “Intended and Unintended Pregnancies Worldwide in 2012 and Recent Trends”.
4 Aoun et al. Effects of age, parity, and device type on complications and discontinuation of intrauterine devices. Obstetrics & Gynecology (123;3) 2014, 585-592
5 Madden et al. Association of age and parity with Intrauterine device expulsion. Obstetrics & Gynecology (124;4) 2014, 718-726