Engaging Global Stakeholders to Expand Access to the LNG-IUS

Sally Stephens, Senior VP, Corporate Development, Medicines360
Medicines360 Mission

Medicines360 is a global nonprofit pharmaceutical company with a mission to expand access to high quality medicines for all women, regardless of their socioeconomic status, insurance coverage, or geographic location.
Our First Product: A Hormonal Intrauterine System (LNG-IUS)

**T-Shaped, drug loaded IUD**

- Total drug load: **52 mg of levonorgestrel (LNG)**
- Designed for ~**20 mcg/day** LNG elution rate
- > **99% effective for up to three years***, high continuation rate at one year
- No scalpel or lidocaine needed for insertion or removal

**Loaded with an insertion device (2 options):**

**Option 1: Approved by multiple SRA’s**
- 2-handed Inserter

**Option 2: In Development**
- Medicines360 Proprietary 1-handed inserter

Note: * U.S. study is ongoing; Medicines360 will seek approval for duration of use beyond 3 years
Medicines360’s LNG-IUS Has Been Approved in ~20 Countries

• Approved by the U.S. FDA in February 2015 for 3 years of contraception*; marketed as Liletta®

• Approved by the MHRA for 3 years of contraception and menorrhagia; marketed as Levosert

• M360 creating a global brand name to be used where we have distribution rights

Note: * U.S. study is ongoing; Medicines360 will seek approval for duration of use beyond 3 years
Medicines360 Partners with Allergan to Manufacture and Distribute Its LNG-IUS

**In the U.S.**

- Allergan markets the LNG-IUS as Liletta® across the private and public sectors
- Medicines360 provides supplemental training, education and awareness in the U.S. public sector
- Liletta® is available at a commercial price as well as at a lower price of $50 to health clinics in the public sector

**Internationally**

- **Medicines360 has exclusive distribution rights in 61 countries (Africa and South/Southeast Asia)**
- Medicines360 and Allergan share rights in another 63 countries
- Allergan has exclusive distribution rights in the remaining countries
- M360 negotiated transfer price from Allergan (price varies by order size, ~$15/unit at an order of 100K units)
Medicines360’s LNG-IUS Rights Globally

*Parties to discuss commercialization, expectation that Allergan sells in private sector and M360 sells in public sector
Medicines360 Partnerships for Global Access to the LNG-IUS

Partnering for R&D

- Medicines360 led the U.S. contraceptive clinical trial for the LNG-IUS
- Allergan created the product and manufactures the product in Belgium
- Medicines360 has negotiated an affordable transfer price for commercialization in developing countries
A Global Stakeholder Engagement Strategy

Medicines360 Vision:
Healthcare for each woman. Access for all women.

Market Assessment & Development
Service Delivery & Commercialization
Regulatory Affairs
Procurement Mechanisms

Broadest Impact in Public and Private Sectors
Market Assessment & Development
KENYA

RHSC Innovation Fund

• Preliminary Market Assessment

• Development of a Comprehensive Product Introduction Strategy

• Modification of MSI training materials

• Negotiation of distribution/price ceiling agreement between MSI and Medicines360
Market Assessment

INDIA

• **Landscape Analysis**
  - Evaluate the potential demand for an effective and affordable LNG-IUS through the public, private and social marketing sectors
  - Interviews with Key Informants

• **Regulatory Assessment**
  - Understand the process for regulatory approval, determine the requirements for in-country clinical trials
Service Delivery & Commercialization

- Engage partners and funders to support LNG-IUS introduction in several countries
  - WCG/PSI for Madagascar (EECO)
  - PSI for Senegal (SIFPO 2)
  - MSI for Kenya (SIFPO 2)

M360 Role

Shared Role

Commercial Partner Role
Regulatory Affairs

- Use SRA approvals as basis for dossiers, collaborate with commercial partners to determine and execute regulatory strategy
- LNG-IUS on the WHO EML (May, 2015)
- Pursue WHO Prequalification, given SRA approvals
- Pursue global harmonization initiatives to create streamlined and efficient product registration across the region
  - SADC - Southern African Development Community
  - EAC - East African Community
Procurement Mechanisms

- Collaborating with WCG and PSI to procure product through USAID’s EECO project
- Initiating discussions with UNFPA for procurement
“Let us commit to work together to improve access to the best contraceptives. For it is only by working together that we will succeed in achieving universal access to contraception and enable women and men to pursue their dreams and decide their own destiny.”

-- Victoria Hale, Founder, Medicines360
Thank You!