

## Longer Acting, Injectable Birth Control

*Formulation for uniformly sized, stabilized, long acting birth control*

### Intellectual Property ID Number 255

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### Field

Injectable Birth Control

### Technology

Formulation and method for a long lived, stable form of LNG-B

### Key Benefits

Less visits to the OBGYN/year

### Stage of Development

Successful animal model test

### Status

Seeking sponsored research and licensing partners

### Patent Status

Patent Pending

### Injectable Birth Control

Injectable contraception eliminates the need for daily treatments with conventional birth control pills, which currently has a greater acceptance in some economically disadvantaged countries. This formulation patent enables longer times, up to six months, between injections to decrease visits to doctor's offices. The longer times may make the method more acceptable in affluent countries, especially if self-injection becomes an option.

### Description

The major advantages of injectable birth control are convenience, the high degree of pregnancy prevention, reversibility, and patient compliance, which has resulted in increasing popularity. These hormonal injections have recently become more popular in Africa and lower-income Latin American countries.

Levonorgestrel butanoate (LNG-B) was originally synthesized in the 1970's through collaboration between the WHO and NIH as a prodrug that becomes an active contraceptive *in vivo*.

This formulation method offers a way to produce uniform particles of LNG-B (5-50  $\mu\text{m}$ , preferably 10-30  $\mu\text{m}$ ) that do not aggregate during storage. This increases the half-life in the body which increases the time between injections. The uniformity also decreases the amount of steroid injected, which decreases the likelihood of side effects. Clinical testing has been validated in non-human primates. Additionally, this treatment may also be suitable for female reproductive disorders. Although not proven, this treatment may be a way to help decrease the reported two fold increase in HIV infection rates (as compared to other methods) of the Depo-Provera injectable form of birth control.

### Market

The global market for all female contraceptives was \$4.71 billion in 2014 with a predicted expansion to \$7.09 billion by the end of 2019. The market is driven by the prevention of unwanted pregnancies, approximately 70% in the US (higher in the teenage population) and approximately 16% globally.

The Population Reference Bureau data on the world's poorest 69 countries shows injectable are used 5% of the time. The highest use was in sub-Saharan Africa where 38% of women using modern birth control methods used injectable contraceptives and implants.

There are several injectable birth control treatments, including Depo-provera, and the more widely used Noristerat. Pfizer currently markets a 13 week self-injectable form of Depo-provera called Sayana Press in England. In the US, less than 3% of women using birth control selected an injectable formulation. The three main reasons cited were lack of knowledge, fear of side effects or health hazards, and satisfaction with their current method. The most likely patients to indicate they intended to use injectables included: single women, women with no college education, women with children, women wanting to have a child (or another child), and women with positive attitudes toward the effect of using an injectable.

### Opportunity

EVMS is seeking sponsored research and/or licensing partners to commercialize this technology.