Novel Oral Contraceptive

(Nuvocept™)

PHARMACEUTICAL PRODUCT OPPORTUNITY

An Optimal Multiphasic Regimen – the Safest Product of its Class

We have developed and patented a potential market leader - an improved European "Gold Standard" in oral contraception

Nuvocept™

Robust hormonal balance and safest progestin – superior product label

In some countries could be approved with no new clinical data

In the US Nuvocept could generate hundreds of millions in annual sales

OUR INNOVATION AND PROPRIETARY POSITION

Gradual, balanced increase in both progestin and estrogen doses.

Three patent applications developed with a top intellectual property firm.

Constant progestin-to-estrogen ratio during any phase of the dosing period.

Patents are currently being pursued in the US and EU.

New and different multiphasic contraceptive with no similar predecessors

A 10-year protection is already secured in Germany.

The patent applications are developed and owned by the ARSTAT's principal –Arkady Rubin, PhD. In the area of contraception, Dr. Rubin contributed to multiple successful NDAs and co-authored numerous publications. He evaluated clinical data to justify the development of Ortho Tri-Cyclen Lo®, designed its unique Phase III trial and was recognized as a co-inventor (US Patent 6214815, EU Patent 1140109) of this best-selling oral contraceptive in the US (>$480M, 2014).

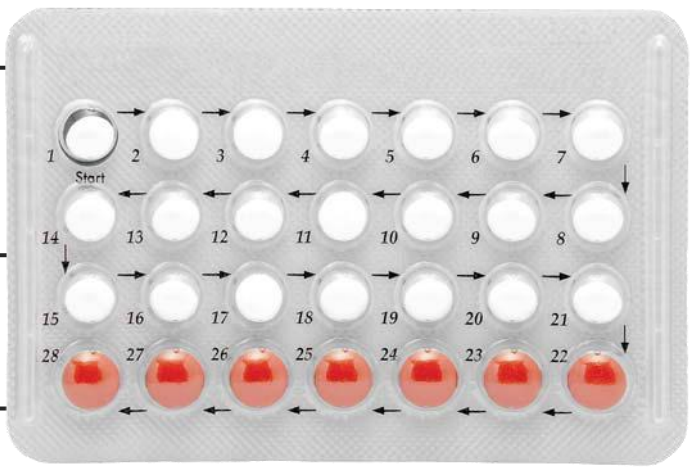
SCIENTIFIC RATIONALE

Major reasons to develop new oral contraceptives:

The FDA-mandated labeling changes regarding the risk of venous thromboembolism (VTE) for pills with modern progestins (e.g., Yaz®, Yasmin®)

Inferior efficacy and cycle control of pills with low doses of estrogen (ethinyl estradiol, EE)

Search for a safe multiphasic contraceptive regimen that mimics a woman's natural cycle



CLINICAL ADVANTAGES

- Nuvocept contains the safest progestin (levonorgestrel, LNG) with the lowest risk of VTE and a favorable label vs. most of available contraceptives, including current US market leaders.
- Nuvocept will be more efficacious vs. a low-dose LNG/EE formulation and safer than a high-dose monophasic LNG/EE pill (a European "Gold Standard" in oral contraception).
- A constant LNG/EE ratio during entire dosing period further reduces hormonal side effects.

DEVELOPMENT DETAILS

In some countries could be marketed in 1.5 - 2 years
Ready for Phase III (if efficacy data required)

Due to its unique dosing pattern, Nuvocept could be approved in some EU countries based entirely on available clinical data for marketed LNG/EE pills (<$2M; <2 years to launch)

If efficacy data required, Nuvocept is ready for a small, low-risk Phase III study in the US (<$20M, 3-4 years to approval)

< 2 Years | **2.5 Years** | **3-4 Years**

In other EU countries, a sole pharmacokinetic study could suffice (<$5M; 2.5 years).

Two preferred dosing formulations; triphasic (first choice) and biphasic

Maximum value if two regimens are developed concurrently, at a typical cost of one.

Known US regulatory precedents, rapid 505(b)(2) NDA

SOLID COMMERCIAL OPPORTUNITY

The US combined contraceptive market exceeds $4B, grows fast, open for new entrants, and increasingly appealing.

Two major reasons:

A very sharp (≈185%) spike in monthly price of leading branded contraceptives: from $41 (2006) to $117 (2015)

Significant sales volume (>$100M) for each percent of the US market share .

The companies (including big pharma) focus on incremental advances with well-known compounds low R&D costs and a short time to market.

Nuvocept meets all of these criteria.

With some conservative assumptions, our preferred triphasic regimen is expected to capture up to 3% of the US market ($300M/year). This is less than two-thirds of the market share reported for another, predictably inferior, triphasic oral contraceptive, Ortho Tri-Cyclen Lo®.

We are currently evaluating commercial potential of Nuvocept in the EU.

VALUE PROPOSITION

The intellectual property is offered to pharmaceutical companies and venture capital firms.

Although we prefer a sale of the IP, we would also consider out-licensing or other flexible arrangements, including joint development.

CONTACT

Arkady Rubin, *PhD*

arubin@arstatinc.com

347-385-0878