

PRESS RELEASE



Stunning results in First in Human trial with novel LiGalli MedRing 2.0

LiGalli BV, a Dutch based MedTech/Biotech company, focusing on the development of its novel and unique vaginal ring for a wide range of therapies and diagnostics, today announced successful completion of its Phase-I oxybutynin trial.

The company performed a single dose Phase-I study (n=8) with oxybutynin, a therapy for overactive bladder, in liquid formulation in their unique LiGalli MedRing 2.0 at the Centre for Human Drug Research in Leiden, The Netherlands. LiGalli is proud and happy to announce a total of five historical worldwide “firsts” in human vaginal ring drug delivery:

- 1) First in Human trial with the novel LiGalli MedRing 2.0, allowing adjustable personalized administration of medication with remote control
- 2) First vaginal administration of a systemic medication in liquid formulation,
- 3) First confirmation of systemic absorption of microliter dose administration,
- 4) First finding of highly consistent and clinically relevant systemic absorption profiles of oxybutynin after single 3 mg dose.
- 5) First and unmatched favorably low metabolite/parent ratios of oxybutynin.

Overactive bladder is prevalent in 16% of the population and suffers from a high number of side-effects and discontinuations due to the current forms of pharmacotherapy.

These results confirm the confidence of the company that the drug delivery opportunities with this MedRing are multifold, as a wide range of compounds has already shown positive absorption results in preclinical studies.

LiGalli started preparations for follow-up studies with oxybutynin and other compounds, addressing pharmacodynamics and clinical efficacy, first results expected Q3 2021.

“Great that the MedRing now has opened the door to personalized medication for women, monitoring treatment and improvement of therapy based on data” says Maarten Wiegerinck, MD PhD and Director Clinical and Sensing of LiGalli.

“Realization of the MedRing was a great challenge, but we persevered and did it” says Victor Nickolson, PhD, Director Preclinical and Pharma.

The Hague, the Netherlands, February 28th, 2021.

Background and current status of LiGalli's ring

The technical development of the ring has approached its final phase, some extra technical improvements are well underway, afterwards the assembly and production will be kicked off. Demcon is the main engineering partner of LiGalli and they engaged in a highly challenging project to build the ring, with the correct layout, dimensions, functioning and miniaturization. "We are proud to contribute to such a revolutionary and impactful company. Our engineers are incredibly motivated and enthusiastic to make this kind of impact in women's health care. We have high expectations for this product, based on the results of the first studies", says Dennis Schipper, CEO of Demcon.

The functioning of the ring can be watched on LiGalli's website (www.ligalli.nl).

The first clinical application of the MedRing 2.0 is treatment of Overactive Bladder. The frequent side effects of oxybutynin are caused by metabolization of this compound in the liver, mainly after oral medication. Vaginal administration bypasses this effect, as now confirmed in our trial results, and mentioned as the 5th "First".

Intellectual property is protected by a series of 6 filed patents. LiGalli is proud and happy to confirm the granting of its basic ring patent now also in the USA after already being granted by the European patent authorities. This patent covers the uniqueness of the dimensions, basic parts, qualities and functions of the ring. The intellectual property is further protected by 5 other universal patent filings.

Further background about LiGalli's MedRing unique features

Vaginal rings and vaginal drug delivery enjoy a strongly increasing popularity, with > 150 clinical trials visible in a cross-sectional search in the ClinicalTrials.gov database and > 5000 available scientific publications on this topic.

All these vaginal rings currently in development are limited by only being able to deliver a fixed dose, released continuously, and almost exclusively for restricted number of (gynecological) indications. These rings can neither be operated via an app, nor confirm drug compliancy, nor collect data.

In stark contrast with all existing vaginal rings, LiGalli develops a novel and uniquely different vaginal ring. It is the so called LiGalli MedRing 2.0. The ring contains miniaturized elements like a drug container, a pump, a battery, a motor, an antenna, electronics, and sensor(s). Connectivity with a mobile device/telephone allows for adjustment of dose, schedule and timing. The ring is discrete, elegant, invisible and convenient to use.

The ring allows adaptation of dose, schedule and timing, via remote control with the patient's own smart phone. Furthermore, the ring collects and communicates physiological data. The ring is self-insertable and self-removable and is intended to function continuously for 4 weeks. Just to be clear, it is the only MedRing 2.0 in development, as far as publicly known.

Furthermore, the LiGalli ring is equipped with a temperature sensor, recording body temperature while being intravaginally in operation. So, for the first time ever, adherence to the (non-invasive) administration of the prescribed medication is being monitored and confirmed by body temperature recordings of this sensor.

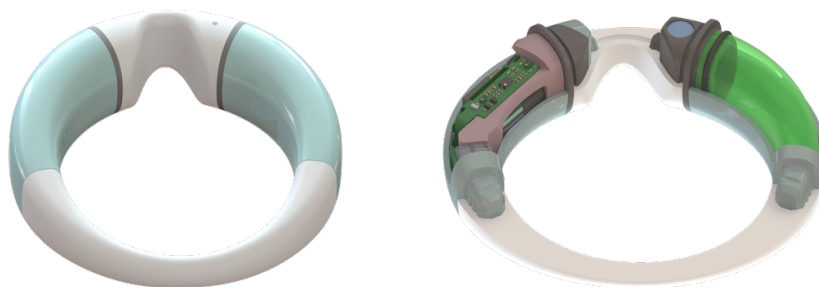
Moreover, the medical doctor can accurately change the schedule and the dose based on the response of the patient to the treatment. This way, the ring allows better personalization and customization of the treatment of the patient.

The drug delivery part can function as a platform for many kinds of drug administrations for various systemic diseases. LiGalli's trial data confirm the vagina as an ideal environment for inbound (drug delivery of various compounds for all kinds of diseases) and outbound (several diagnostic) purposes .

The diagnostic part of the ring opens a completely new window for capturing all kinds of physiological and therapeutic data, and for analyzing objective patient treatment data. Finally, the integration of both drug delivery and diagnostic parts of the ring is a realistic, promising, and intriguing possibility.

"We now have a product, our ring keeps amazing us by its possibilities and potential, even far beyond our wildest dreams" says Willem de Laat CEO.

LiGalli is founded in 2014 by Willem de Laat MD, PhD, former CMO of Organon Pharmaceuticals (part of AkzoNobel) and manager of the Dutch Top Institute Pharma.



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