# **OLAR®:** A Novel Oral Long Acting Release (OLAR®) platform

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### Introduction

Oral administration is the most commonly used drug delivery route for the majority of conditions. Nevertheless, oral formulations are limited and challenged by physicochemical barriers and highly variable residence times. Gastric retention is a widely employed approach to retain the dosage form in the stomach for an extended period of time, releasing the drug slowly and addresses many challenges associated with conventional oral delivery, including a narrow absorption window, poor bioavailability and dose fluctuations<sup>1</sup>.

## **Methods**

The OLAR<sup>®</sup> platform\* (see <u>https://www.clexio.com/forpeople/#pipeline</u> and *Figure 1* ) is being developed for oral administration, using known pharmaceutical excipients and a process that combines hot melt extrusion and injection molding. Drug tablets are manufactured by standard pharmaceutical processes and are independent from the OLAR<sup>®</sup> platform (*Figure 2*). The OLAR<sup>®</sup> has been successfully tested in pre-clinical and early (phase 1) clinical studies.

radiographic examination revealed that the OLAR<sup>®</sup> was fully open in the stomach within 10 minutes of administration and still present in the stomach at least 8 hours later (*Figure 4*). A prolonged pharmacokinetic drug profile was demonstrated with stable plasma levels of the drug for more than 8hrs (*Figure 5*). The administration of OLAR<sup>®</sup> was safe, well tolerated and without concerns over swallowability.

Figure 3: In-Vitro: Extended Release profile achieved by slow dissolution of the inner tablets in the OLAR® Once placed in the OLAR®, the Immediate Release tablets provide an Extended Release profile











#### **Results**

In-vitro OLAR<sup>®</sup> dissolution assays resulted in an extended release profile achieved by slow dissolution of the tablets within the OLAR<sup>®</sup> (*Figure 3*). Preclinical safety and imaging studies confirmed gastric retention and no local or systemic toxicities. In Phase 1 Placebo and PK studies,

# Conclusions

The OLAR<sup>®</sup> is being developed to be an orally-administered, non-invasive, novel platform to facilitate efficient drug absorption and lower drug plasma fluctuations with continuous drug release from the stomach. The OLAR<sup>®</sup> versatility is suitable for multiple APIs, enables high drug loading and is now being utilized for the development of the first dedicated oral treatment for PD nocturnal problems and morning akinesia.

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<sup>1</sup> Tripathi J, Thapa P, Maharjan R, Jeong SH. Current State and Future Perspectives on Gastroretentive Drug Delivery Systems. Pharmaceutics. 2019 Apr 20;11(4):193. \* OLAR is currently in development and is not yet approved for commercial distribution

