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To All Media Outlets

## ID-Capsule™ Technology Display at Interphex Japan = Developing Cutting-Edge Capsules That Improve Treatment Adherence =

At the 21st Interphex Japan (held July 3-5, 2019), Qualicaps (headquartered in Yamatokoriyama City in Nara Prefecture and led by CEO Shoji Mori) will present etectRx's ID-capsule™ technology, the first technology of its kind in Japan, as a tool for improving the traceability of capsule formulations of drug products from distribution through patient ingestion.

The ID-capsule system is a technology that can help to improve the measurement of medication adherence through the use of a hard capsule that incorporates ID-Tags™ designed and provided by the US company etectRx (based in Florida). Qualicaps and etectRx have had a collaborative relationship since 2015. The ID-Tag™, an ingestible sensor, which is housed in a hard capsule, includes an IC chip and reacts with stomach acid to power a battery and emit a low-power signal. When the hard capsule dissolves in a patient's stomach, the ID-Tag™ emits a signal that makes it possible, by accessing a database via a mobile network, to confirm in real time that a patient has actually ingested the drug dose that was contained in the capsule. The use of this system is expected to make it easier to manage patients' treatment adherence and improve the precision of clinical study data, among other benefits.

Multiple clinical studies have already been conducted in the United States using the ID-Cap™ system, and etectRx has been collecting data to demonstrate the effectiveness and safety of the ID-capsule™ system as a medical device. Clinical studies are ongoing to demonstrate improved treatment adherence using this measurement tool, and etectRx is seeking FDA clearance for marketing the device in the United States. However, incorporating the ID-Tags in hard capsules requires advanced capsule manufacturing technology. Qualicaps has been supporting the development of etectRx's ID-capsule™ technology with Qualicaps' capsule formulation technologies, including its high-quality hard capsules and filling machines.

Qualicaps will continue to promote the development of ID-Tag™-containing hard capsules and ID-Tag™ hard capsule filling machines, and realize the early adoption of this technology.

**Direct all inquiries to:**

**Qualicaps**

**General Affairs and Human Resources Department**

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## **Picture of an ID-capsule™**



## **Overview of Qualicaps**

Qualicaps has been contributing to human health and welfare by supplying capsule/drug product equipment to pharmaceutical manufacturers and other clients around the world. Qualicaps' has the No. 1 market share of capsules used in drug products in Japan, and is No. 2 worldwide. Qualicaps also has one of the highest market shares in the industry for the equipment that is used on drug product production lines. Qualicaps' plant-based HPMC capsules, which are becoming the market standard, were initially developed in Japan by Qualicaps 20 years ago for medical use.

For more detailed information about Qualicaps, visit <http://www.qualicaps.co.jp/>.

## **Overview of etectRx**

etectRx is a privately held digital health company, based in Gainesville, Florida, USA, seeking to advance patient medication

adherence and improve medication ingestion tracking technology. etectRx's flagship product, the ID-Cap™ System, is an ingestible event marker that is comprised of a gelatin capsule containing a wireless ingestible sensor, which transmits signals to a wearable reader and then to a smartphone-based app and secure cloud-based server to enable reliable tracking of ingestion events. To learn more about etectRx, visit <http://etectrx.com/>.

etectRx submitted a premarket notification (510(k)) application with the U.S. Food and Drug Administration (FDA) for its ID-Cap™ System as an ingestible event marker in late 2018 and anticipates FDA clearance for marketing in 2019. The ID-Cap™ System is currently only available for investigational use in IRB-approved clinical studies.