



## **CREDENCE MEDSYSTEMS ANNOUNCES A SIGNIFICANT MILESTONE TOWARDS SCALING MANUFACTURING CAPABILITIES**

**MENLO PARK, CA, USA, 22 JANUARY, 2024**

**Credence MedSystems, an innovator of drug delivery systems that solve unmet market needs for the pharmaceutical industry, announced today that it has successfully completed Factory Acceptance Testing (FAT) for production of its Companion® injection device platform on the Company's new Clinical Assembly Line.**

Completion of FAT represents a significant milestone in expanding manufacturing capabilities for the Company's injection systems. Credence selected Mikron Automation, a leading automation equipment supplier, to produce the Clinical Assembly Line using its MiniCell automation platform. For ongoing product manufacturing, the Line will be transported from Mikron's Denver facility to the Letterkenny, Ireland plant of pharma and medical device contract development & manufacturing (CDMO) firm Phillips-Medisize, a Molex company.

"This is a critical step on the path to GMP clinical supply and subsequent commercial production," stated Jeff Tillack, Credence's Chief Operating Officer. "The Clinical Assembly Line achieves two major goals. It enables our Pharma customers to advance to use of our devices in humans and it provides vital learnings as we scale to much higher commercial production volumes."

The Clinical Assembly Line's anticipated production capacity of 500,000 units per line per year is designed to supply the Company's pharma customers with GMP product to support Combination Product development activities such as device verification & validation, drug stability studies and clinical trials. "This is truly enabling for our Company and our customers," said John Merhige, Credence's Chief Commercial Officer. "We have been working with a wide array of customers, including two-thirds of the world's 20 largest pharmaceutical and biologics manufacturers. Our products have been evaluated in numerous customer-sponsored user studies and stability studies. With this Clinical Assembly Line capability, we can support the natural progression of these programs towards the clinic and commercial use."

The Clinical Assembly Line will produce the Credence Companion® and Credence Dual Chamber Syringe Systems in a wide array of configurations to support many therapeutic applications. One example of the Line's capability relates to the Credence Dual Chamber Sequential Syringe. This system allows two liquid drug products to be stored separately in one syringe barrel and delivered with a single injection. It has the

potential to enable delivery of critical therapeutics in applications such as obesity, diabetes, vaccines and others, where there are emerging needs to combine two drug products that cannot be formulated together.

The Company has previously announced strategic investments from Novartis and Molex Ventures. As Novartis and other pharma companies look to enhance the safety and user experience of their patients, caregivers, and healthcare professionals during administration of injectable medications, these strategic investments support ramping of Credence's manufacturing capabilities. This milestone is consistent with that goal.

### **About Credence MedSystems, Inc.**

*Credence MedSystems is an innovator of drug delivery systems that solve unmet market needs for the pharmaceutical industry. Credence's philosophy of Innovation Without Change allows pharma manufacturers to solve challenges in injectable drug delivery while preserving their existing processes, sourcing strategies and preferred primary package components. The Companion® family of syringe systems provides critical safety and usability features with superior sustainability value. The Dual Chamber platform offers simplified delivery of medications requiring separation of their components during storage. The Credence Connect™ brings digital connectivity to any prefilled syringe. Metered dose systems and other novel devices address the needs of specific markets such as ophthalmic delivery and aesthetic applications.*

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