



## **ten23 health® kickstarts new era with launch of industry-first robot-assisted pilot non-GMP sterile filling in its Basel facilities**

Customers can now accelerate new product development with early access to non-GMP but clinically representative liquid and lyophilized batches. The pilot line is easy to access, reduces costs, and allows the use of material that would not be suitable for GMP processing.

The pilot line:

- Is completely downscaled and robot-assisted
- Enables non-GMP product development, e.g. with new primary packaging implementation, stopper setting evaluations, etc

**Basel, Switzerland, May 12, 2025** – ten23 health®, the human-centric and sustainable contract development, testing and manufacturing organization (CDTMO), today announced the launch of its “Line 0” (non-GMP) pilot sterile fill & finish services from its Basel (BASE®) facilities. The first-of-its-kind, custom-designed and purpose-built pilot sterile filling line is a co-development with Optima. The robot-based, small-scale filling machine is suitable for ready-to-use (RTU) and bulk containers, including vials, syringes, and cartridges, in combination with a 1.1 m<sup>2</sup> sized freeze-dryer (lyophiliser).

With development and preclinical costs increasingly under pressure, Line 0 offers the pharmaceutical industry an exciting new option for a wide range of key tasks. Customers will be able to take advantage of perfectly scaled-down, time- and cost-efficient process development services, and access aseptically produced drug product batches that do not require GMP grade. The pilot line avoids the extra costs and constraints of performing such activities in GMP manufacturing facilities or using non-representative equipment in labs.

*“We will add significant speed and value to our customers’ projects with this innovative technology and the additional services that seamlessly integrate with our sterile GMP manufacturing offerings. We can now provide complete solutions from the development and preclinical scale to clinical and commercial manufacturing scale, with purpose-built scaling and transfer in mind,”* explains Prof. Dr. Hanns-Christian Mahler, Chief Enablement Officer (CEO) at ten23 health.

Operated under the ISO9001 quality management system, Line 0 is designed to provide aseptically filled batches which may be required for specific purposes such as the implementation of novel processes or primary packaging, stability testing, analytical reference materials, and preclinical study material.

The new offering is compatible with novel primary packaging as well as related process development and characterization assessments for filling, stopper setting and lyophilization processes. It seamlessly integrates different manufacturing scales at ten23,



from the new Pilot “Line 0” (non-GMP) in BASE® (Basel) to the VIVA1® and VIVA2® GMP fill& finish lines (Visp), all of which Isolators in Class C environment in Annex 1 GMP compliance: “Line 1” (for clinical and commercial use using ready-to-use (RTU) container) “Line 2” (for large-scale commercial and possibly clinical use using RTU container), to “Line 3” (for clinical and commercial bulk-vial liquid or lyophilizate manufacturing). All sterile manufacturing lines are based on Optima equipment platforms, enabling easy scale-up and ensuring they are fit-for-purpose for the specific needs of each customer.

*“With the addition of the pilot line to our offering we can support our customers by supplying liquid and lyophilized batches early on in their development timeline, with a setup and process representative of later clinical or commercial GMP batches. Compatibility with our GMP filling lines allows seamless process scaleup and reliable supply throughout our customers’ molecules’ lifecycles,”* adds Dr. Susanne Jörg, Chief Customer Delivery Officer (COO) at ten23 health.

### **About ten23 health**

ten23 health®, located in Basel and Visp, Switzerland, is the human-centric and sustainable strategic partner of choice for the pharmaceutical industry and biotech start-ups: we develop, manufacture, and test modern medicines. We support our clients in developing differentiated, stable, usable, and safe injectable treatment options for patients. ten23 health® combines the latest scientific findings with proven and tested world-class industry and regulatory expertise to forge new paths for supporting clients. We provide our innovative services in a fair and sustainable manner, respecting people’s health and the future of our planet. ten23 health® is a B-Corp member and solidly financed through the long-term commitment of 3i Group, an internationally reputable equity partner.

### **About the company’s name**

The numeric value for the number of molecules in a sample of one mol is called Avogadro constant and equals  $6.022 \cdot 10^{23}$ . Gram quantities of material contain the incredible number of  $10^{23}$  atoms, which was an important discovery to understand the composition of matter: The world is built from small units, and not a homogeneous mass.

### **About 3i Group**

3i is an investment company with two complementary businesses, Private Equity and Infrastructure, and invests in mid-market companies headquartered in Europe and North America. 3i’s Private Equity team provides investment solutions for growing companies, backing entrepreneurs and management teams of companies with an EV typically between €100m – €500m. 3i backs international growth plans, providing access to its network and expertise to accelerate the growth of companies across the consumer, healthcare, industrial and private label, and services and software industries.

### **Media contacts:**

**ten23 health:** Marija Petrovic; marija.petrovic@ten23.health; +41 78 694 87 33

**3i Group:** Kathryn van der Kroft, Kathryn.VanDerKroft@3i.com; +44 20 7975 3021

