

Lonza Launches SimpliFiH™ Services – an Integrated First-in-Human Service Package for Poorly Soluble Small Molecules

- Integrated drug substance, solid-state characterization, and phase-appropriate drug product provides simplified and accelerated route to first-in-human studies
- Proprietary bioavailability technology selection methodologies streamline solubility screening requirements
- Simplified agreement structures further facilitate rapid first-in-human timelines

Quote from Gordon Bates, President, Chemical Division, Lonza Pharma & Biotech:

“Chemistry is core to Lonza, and we continue to innovate and invest in flexible small molecule services and site network infrastructure that benefit our customers. We are pleased to launch SimpliFiH Solutions, which integrates our core capabilities and expertise in bioavailability enhancement and drug substance development, and accelerates the first-in-human pathway for candidate molecules.”

Quote from Dr. Christian Dowdeswell, VP and Head of Dosage Forms & Delivery Systems, Lonza Pharma & Biotech:

“The majority of preclinical candidate molecules require bioavailability enhancement, many even for early phase studies. We have designed SimpliFiH Services to meet the needs of customers for flexible, truly integrated packages that address the bioavailability challenge in a time- and cost-efficient manner.”

Basel, Switzerland, 30 April 2019 – Lonza Pharma & Biotech announced the launch of SimpliFiH™ Services, integrating its leading expertise in addressing bioavailability challenges with drug substance, solid-state characterization and drug product for first-in-human studies. As drug discovery and development accelerate and solubility and dissolution rate challenges become more complex, new solutions are required to reduce the timeline from initial idea to a first-in-human clinical verification.

Lonza's new service package has been specifically designed for innovator companies that have solubility-challenged molecules and require drug substance and drug product services for early-stage development and first-in-human studies. Streamlined service agreement templates specific to the SimpliFiH package have also been developed to further reduce time, cost and complexity for these studies. This new offering demonstrates Lonza's continued commitment to constant innovation and adding value for its customers.

The foundation of SimpliFiH Services is the company's proprietary bioavailability enhancement technology selection methodology. This methodology encompasses databases and models based on more than 25 years' experience advancing thousands of molecules to phase I across all key enabling technologies – particle size reduction, solid dispersions and lipid-based formulations. By using this methodology, a single enabling approach for early first-in-human studies can be rapidly identified without extensive solubility screening which thereby reduces early phase clinical timelines and API requirements.

SimpliFiH Services encompasses the key drug substance and drug product components required for first-in-human studies for small molecules: drug substance development and supply, solid-state characterization/bioavailability enhancement, and phase-appropriate drug product in powder-in-capsule, powder-in-bottle, liquid-filled hard capsule or tablet format.

Basic analytical services inclusive of stability studies are included in the SimpliFiH Services package. Regulatory services for supporting, consulting on or writing IND and IMPD are available to support first-in-human requirements. More details can be found [here](#).

About Lonza

Lonza is an integrated solutions provider that creates value along the Healthcare Continuum®. Through our Pharma Biotech & Nutrition segment and our Specialty Ingredients segment businesses, we harness science and technology to serve markets along this continuum. We focus on creating a healthy environment, promoting a healthier lifestyle and preventing illness through consumers' preventive healthcare, as well as improving patient healthcare by supporting our customers to deliver innovative medicines that help treat or even cure severe diseases.

Patients and consumers benefit from our ability to transfer our pharma know-how to the healthcare, hygiene and fast-moving consumer goods environment and to the preservation and protection of the world where we live.

Founded in 1897 in the Swiss Alps, Lonza today is a well-respected global company with more than 100 sites and offices and approximately 15,500 full-time employees worldwide at the end of 2018. The

company generated sales of CHF 5.5 billion in 2018 with a CORE EBITDA of CHF 1.5 billion. Further information can be found at www.lonza.com.

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