

## Product News

### **Lonza Releases Second-Generation Immunogenicity Assessment and Optimization Platform for Development of Therapeutic Proteins, Vaccines and Cell Therapies**

**Basel, Switzerland, 07 September 2016** – Lonza, a global leader in biological development and manufacturing, announced today the release of its second-generation immunogenicity assessment platform. The upgraded platform consists of state-of-the-art *in silico* and *in vitro/ex vivo* technologies to evaluate immunogenicity risk during the pre-clinical development of therapeutic proteins. In the context of vaccine and cell therapy development, the platform enables the rational design and testing of optimal immune responses in healthy donor or patient populations.

This second-generation platform provides a comprehensive toolbox to assess customers' early-stage candidates for immunogenicity risk. The platform also provides tools for deimmunization to reduce immunogenicity risk through the identification and removal of T cell epitopes. Major components of the upgraded platform include:

- Epibase® *in silico* version 4 immunogenicity platform supports T cell epitope prediction with enhanced accuracy by the addition of a TCR facing filter
- MHC-associated peptide proteomics (MAPPs) identify HLA binding peptide profiles from whole proteins naturally processed and presented by human dendritic cells
- Enhanced T cell activation assays confirm T cell epitopes identified *in silico* or MAPPs with highly sensitive CD4 and CD8 T cell re-stimulation assays using a dual-color FluoroSpot readout
- Cytokine release assay (CRA) assesses risk of the candidate inducing a dangerous cytokine response with cytokine profiles assessed by Luminex® reagents.
- Pre-existing antibody assessment detects total and antigen specific IgA, IgG, IgE, and IgM secreting B cells using the B Cell FluoroSpot Assay

Lonza Ltd  
Muenchensteinerstrasse 38  
CH-4002 Basel  
[www.lonza.com](http://www.lonza.com)

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Together with Lonza's manufacturability assessment tools and non GMP material supply, it is possible to identify potential risks during late discovery/early development and select a lead candidate with an optimal product profile. Furthermore, the highly diverse platform of primary cell assays also provides an assessment of the immune response in a fully human platform prior to clinical trials.

"Since its introduction more than 15 years ago, we have continuously improved our Epibase® immunogenicity platform," said Karen Fallen, Head of Lonza's Clinical Development & Licensing Business Unit. "Our comprehensive toolbox combined with our capability to provide material suitable for preclinical testing supports our customers' development needs from early design to cGMP production. Lonza is the only CDMO that helps our customers progress their candidates seamlessly through the discovery and development process."

### About Lonza

Lonza is one of the world's leading and most-trusted suppliers to the pharmaceutical, biotech and specialty ingredients markets. We harness science and technology to create products that support safer and healthier living and that enhance the overall quality of life.

Not only are we a custom manufacturer and developer, Lonza also offers services and products ranging from active pharmaceutical ingredients and stem-cell therapies to drinking water sanitizers, from the vitamin B3 compounds and organic personal care ingredients to agricultural products, and from industrial preservatives to microbial control solutions that combat dangerous viruses, bacteria and other pathogens.

Founded in 1897 in the Swiss Alps, Lonza today is a well-respected global company with more than 40 major manufacturing and R&D facilities and approximately 9,800 full-time employees worldwide. The company generated sales of CHF 3.8 billion in 2015 and is organized into two market-focused segments: Pharma&Biotech and Specialty Ingredients. Further information can be found at [www.lonza.com](http://www.lonza.com).

### Lonza Contact Information

Lonza Group Ltd  
Head Investor Relations  
Dirk Oehlers  
Tel +41 61 316 8540  
Fax +41 61 316 9540  
[dirk.oehlers@lonza.com](mailto:dirk.oehlers@lonza.com)

Lonza Group Ltd  
Head Corporate Communications  
Dominik Werner  
Tel +41 61 316 8798  
Fax +41 61 316 9540  
[dominik.werner@lonza.com](mailto:dominik.werner@lonza.com)

Lonza Group Ltd  
Head External Communications  
Constance Ward  
Tel +41 61 316 8840  
Fax +41 61 316 9840  
[constance.ward@lonza.com](mailto:constance.ward@lonza.com)

Lonza Ltd  
Muenchensteinerstrasse 38  
CH-4002 Basel  
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Certain matters discussed in this news release may constitute forward-looking statements. These statements are based on current expectations and estimates of Lonza Group Ltd, although Lonza Group Ltd can give no assurance that these expectations and estimates will be achieved. Investors are cautioned that all forward-looking statements involve risks and uncertainty and are qualified in their entirety. The actual results may differ materially in the future from the forward-looking statements included in this presentation due to various factors. Furthermore, except as otherwise required by law, Lonza Group Ltd disclaims any intention or obligation to update the statements contained in this release. Epibase is a Lonza trademark, registered in USA and EU. Luminex is a Luminex Corporation trademark.