Influenza Titer on Chip® Now Available as Robust Flu Vaccine Potency Assay

BOULDER, CO--(Marketwired - October 21, 2014) - InDevR, a Boulder-based life science company, announced today that version 1.0 of Influenza Titer on Chip (Flu-ToC™) is now available for purchase as a complete kit. Flu-ToC is used as an alternative to single radial immunodiffision (SRID) for rapid quantification of influenza hemagglutinin protein in flu vaccines. As summarized in a PLOS ONE manuscript published on October 20th (*"Titer on Chip: New Analytical Tool for Influenza Vaccine Potency Determination";* see http://dx.plos.org/10.1371/journal.pone.0109616), Flu-ToC exhibits good correlation with current gold standard methods but is significantly faster and more robust.

Flu-ToC utilizes a panel of subtype-specific and broadly-reactive antibodies that enable reliable quantification of hemagglutinin (HA) over a range of years. Flu-ToC can be used to quantify HA protein in almost any medium, including crude extract, bulk drug substance, and multivalent drug product. The assay has been shown to work with split viruses, virus like particles, and recombinant HA.

Titer on Chip technology was developed with support from the National Institute of Allergy and Infectious Diseases (NIAID, grant R43 AI102318) as part of the U.S. Department of Health and Human Services (HHS) *Influenza Vaccine Manufacturing Improvement* program. Flu-ToC was recently selected by HHS as 1 of 5 techniques to be evaluated by members of the International Federation of Pharmaceutical Manufacturers & Associations as an alternative to the current time-consuming gold standard method (SRID) for vaccine potency determination.

"Based on results from our testing service, launched in July of this year, it is clear that vaccine producers will realize tremendous time and cost-savings by using Flu-ToC to determine functional protein content in seasonal flu vaccines," said Dr. Kathy Rowlen, InDevR's CEO.

Dr. Indresh Srivastava, Vice President of Product Realization at Protein Sciences Corporation, whose innovative Flublok® influenza vaccine was approved in 2013 by the FDA for the prevention of seasonal influenza, noted: *"The blinded study we conducted in collaboration with InDevR demonstrated that Flu-ToC exhibits good correlation with standard methods for our recombinant vaccines, even for in-process samples collected at different stages of development. As an alternative to SRID it is rapid and quantitative, with results available within hours rather than days."*

In addition to Flu-ToC for seasonal flu vaccines, with Phase 2 support from the NIAID InDevR is developing advanced versions of the assay for use with potential pandemic strains of influenza and for high throughput applications. ToC can also be adapted for other vaccines. According to Rowlen*"With appropriate changes to the reagents, the Titer on Chip platform could be used to determine potency for any vaccine. For example, in response to the recent outbreak we are now exploring application of Titer on Chip to Ebola vaccines and biotherapeutics."*

About InDevR

InDevR has a demonstrated commitment to innovative solutions for the life science industry. With focus on enhancing vaccines and other biotherapeutics, InDevR has emerged as a leader in progressive new analytical technologies that enable accelerated development and manufacturing of these life-saving products. For more information about the company and products, please visitwww.indevr.com or call 303-402-9100.

About Protein Sciences Corporation

Protein Sciences Corporation is a vaccine development and protein production company with locations in CT and NY that is dedicated to saving lives and improving health through the creation of innovative

vaccines and biopharmaceuticals. Our proprietary BEVS technology provides a fast, reliable and inexpensive platform for the production of high quality recombinant proteins, making it a powerful tool for producing vaccines and therapeutics when they are needed most. In addition to influenza, we are working closely with the U.S. government to develop a protein-based vaccine for Ebola to help combat the current outbreak. Our technology avoids any need to work with the pathogen itself, so vaccine production is safe. BEVS technology is covered by broad patents that include our proprietary *expres*SF+® cell line that we use to make all of our products. Learn more atwww.proteinsciences.com and www.flublok.com.

HHS is not responsible for the contents of this release. The statements contained in this release do not constitute endorsement or recommendation by the U.S. Government or HHS.

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