

Pressmeddelande den 28 december 2015

Informationsbrev till aktieägarna från Protein Sciences, december 2015

Protein Sciences Corporation (Protein Sciences) har distribuerat ett nytt informationsbrev till sina aktieägare. Protein Sciences har godkänt att Mertiva offentliggör detta informationsbrev. Informationsbrevet innehåller en redogörelse för de viktigaste händelserna i bolaget samt oreviderade siffror för perioden januari-september 2015 och är bifogat till detta pressmeddelande.

Informationsbrevet innehåller även pressmeddelanden, vilka tidigare publicerats på Protein Sciences hemsida.

Protein Sciences avser att distribuera informationsbrev kvartalsvis till sina aktieägare. När Mertiva erhåller sådana informationsbrev avser Mertiva publicera dessa.

För ytterligare information, vänligen kontakta:

Andreas Bergsten, VD Mertiva AB info@mertiva.se 070-5673670

Om Mertiva

Mertiva AB är ett investeringsföretag som i huvudsak består av innehav i Protein Sciences Corporation och Mercodia AB.

Mertiva-aktien är listad på NGM:s handelsplats Nordic MTF (kortnamn: MERT MTF).

Mer information finns på www.mertiva.se.

Denna information offentliggörs enligt lagen om värdepappersmarknaden, lagen om handel med finansiella instrument eller krav ställda i noteringsavtal.



December 2015

To Our Shareholders:

The flu season is upon us and consequently the fourth quarter has been a very active one for your Company. The chief highlight was that our Mexican partner, Liomont, obtained approval from the Mexican regulatory agency COFEPRIS for Flublok®. Flublok is the first recombinant influenza vaccine to be available in Mexico. Significantly, the Mexican authorities also approved a one year shelf life and the use of the Flublok trade name. Representatives from the Protein Sciences team joined Liomont and the National Autonomous University of Mexico at a press conference held in Mexico City to celebrate the approval. The press conference generated substantial awareness for Flublok in Mexico and at home. Our partner Liomont has agreed to purchase one lot and we look forward to the continued development of Flublok in Mexico and other countries.

In December, we submitted a Supplemental BLA for the approval of Flublok Quadrivalent. The sBLA includes the clinical results from our recent study demonstrating that Flublok Quadrivalent was 31% better at protecting against the flu than an egg-derived quadrivalent vaccine. This sBLA also includes a request for approval of our partner, Adimmune, in Taiwan as an additional fill/finish site for Flublok Quadrivalent to increase capacity and presentation in pre-filled syringes. The move to a quadrivalent formulation in pre-filled syringes will make us more competitive in the U.S. marketplace.

We produced approximately 1.2 million doses of Flublok this year (12 lots at Hospira and 6 lots at MassBio) and FDA has released all but one Hospira lot. We have shipped approximately 600,000 doses. Commercial manufacturing for next season has been initiated based on the assumption that the H1 component of the vaccine will not change. We are working with our fill/finish partners to establish firm dates and a minimum plan to produce sufficient drug substance to fill 8 lots (approximately 1.2 million trivalent doses).

We received additional international exposure when our President and CEO, Dr. Manon Cox, was elected as a 2015 Fellow of the International Society for Vaccines (ISV) and our Vice President of Process and Analytical Development, Dr. Indresh Srivastava, who is a leading biochemist and vaccinologist, was nominated to serve on the Executive Board of the ISV.

Flublok: Flublok sales have exceeded the amount sold at this time last year; however, they remain lower than we expected. We shipped approximately 300,000 doses to McKesson and FFF who are identifying channels for these (not pre-ordered) additional doses. Cardinal Health and Henry Schein have been disappointing in their performance as they have fallen well below projections despite special incentives that were offered to their sales representatives.

We have received licenses to ship to over 10 states. These include key states where our distributors have strategic distribution centers. Licensure is in process for several other states that will position us well for additional direct shipping next year. Reimbursement for Flublok remains an area of challenge. We have made important progress in this area but will need to secure additional expert advice to ensure that there is consistency in the reimbursement for Flublok and all barriers to proper reimbursement are eliminated.

The targeted radio campaign in collaboration with iHeart Media has had a measurable impact in Chicago, Dallas and Hartford where sales of Flublok are higher. In addition, iHeart media arranged Flublok specific

interviews that aired in these geographic regions. You can hear one of these interviews here. We ran a national ad this fall directed at independent pharmacists in partnership with the National Community Pharmacists Association (NCPA) and attended several pharmacy and healthcare professional annual meetings.

We are effectively leveraging social media by posting vaccination events of prominent leaders in government and business on our Facebook page and using Twitter to promote those events and relevant influenza topics. Some notable Flublok recipients include: US Senators Blumenthal and Murphy, US Congresswoman Esty, Connecticut Governor Malloy, Connecticut State Senators Bartelomeo, Kennedy and Fasano, New York State Assemblyman Zebrowski, Connecticut State Comptroller, Kevin Lembo, Commissioner of the Connecticut Department of Economic and Community Development, Catherine Smith, Larry McHugh, CEO of the Middlesex Chamber of Commerce and Chair of the University of Connecticut Board of Directors and Coach of the UConn Women's Basketball Team, Geno Auriemma, and Assistant Coach, Shea Ralph. In addition, TV personalities Scott Haney, Channel 3 (CBS Affiliate) and Jim Pellegrino received Flublok on air, Jocelyn Maminta and Diane Smith received Flublok at other venues.

Our mass immunization initiative to offer workplace and community Flublok clinics in Connecticut and the surrounding regions has continued to expand. Health-At-Work (www.health-at-work.net) is a partnership with physicians from Velocity Urgent Care that is a full service vaccination provider that allows employers to customize vaccination clinics for their employees. We secured a significant contract with United Technologies to manage all of their flu clinics and offer Flublok exclusively at all of those clinics.

The Healthy Choices Mobile Vaccination collaboration with Hunters Ambulance, Hartford Healthcare at Home, HealthMed Urgent Care and Health Mart pharmacies has been very successful. The initiative is thriving and the community's response has been great. We partnered recently with the Connecticut Food Bank and it was such a success that we have scheduled additional events during the season. See attached press release. Also, during National Influenza Vaccination Week we partnered with the Department of Public Health for the City of New Haven to educate the community on the public health benefits of flu vaccination and administer Flublok. Both Dr. Martha Okafor, Community Services Administrator, and Dr. Byron Kennedy, Director of Health for the City of New Haven, received Flublok.

We are grateful to our shareholders that supported us by actively asking for Flublok and keeping us informed on experiences in the field. This enabled us to tackle and resolve "real-life" challenges. Thank you for that!

Clinical Trials: Our pivotal Phase 3 trial of Flublok Quadrivalent in ~9,000 adults 50 years of age and older (PSC12) yielded exciting results that confirmed the superior protective efficacy of Flublok over conventional egg-derived inactivated vaccine (IIV4). The data from this trial was presented at the ICAAC conference (largest annual infectious diseases meeting in the world) and a manuscript is under review at the New England Journal of Medicine. A full registration dossier was submitted to FDA on December 4, 2015.

PSC12 was a randomized, observer-blinded trial of RIV4 (Flublok Quadrivalent) vs. IIV4 (Fluarix Quadrivalent) comparing relative vaccine efficacy against laboratory-confirmed, protocol-defined influenza-like illness due to any influenza strain in adults ≥50 years of age. Influenza illness was confirmed by PCR testing of nasal secretions.

Data analysis showed that among adults ≥50 years of age, Flublok Quadrivalent provided better protection against PCR-confirmed influenza and that hospitalization and healthcare utilization for flu appeared to be reduced among Flublok recipients. A smaller trial of Flublok Quadrivalent vs. IIV4 in 1,350 adults 18-49

years of age supported equivalent immunogenicity of Flublok in younger adults and, together, the two trials are expected to support full approval of Flublok Quadrivalent in all adults 18 years of age and older.

Manufacturing: Our manufacturing and quality teams completed 2015/16 commercial production with high marks. This was our third commercial production year in Meriden and the first one in Pearl River. Overall, the manufacturing teams performed as expected with 90% success rate in Meriden and 73% in Pearl River. With experience, the success rate in Pearl River is expected to increase.

In 2015, we produced 18 drug substance bulks in Pearl River and 30 in Meriden. These bulks supported 18 Flublok commercial fills at Mass Bio and Hospira; three Quadrivalent Validation fills at Adimmune (one completed and two scheduled for January 2016); one Pandemic vaccine clinical fill completed in Meriden; and our yield improvement program. In preparation for these fills, 22 mini-formulations were performed to ensure accurate formulations.

A total of 18 Flublok drug product lots were produced and released by the FDA for a total output of over 1.2 million commercial doses. One additional lot is currently under review awaiting final release.

Release of drug product required a tremendous effort from our Quality Team, including testing of inprocess samples, final drug substance, mini-formulations, final drug product and stability samples by QC, and batch record reviews and Lot Release Protocol preparations by QA. Validation efforts focused on the completion of activities to support licensure of our Pearl River facility and activities to support the sBLA for Flublok Quadrivalent filling at Adimmune.

We developed our commercial production plan for the 2016/17 season to ensure that we can release product early in the season. Adjustments will take place based on sales pre-booking in the first quarter of 2016, which is the industry standard.

BARDA: Our BARDA contract is due to expire at the end of this year. As there are funds still remaining, we have applied for a no cost extension until the end of 2016. We are pleased to report that we have fulfilled milestone 11D-2 with the submission of the sBLA mentioned previously. We have also completed step one of the pandemic clinical trial (PSC26) and are in the process of analyzing the data.

Product Development: We were awarded a Phase 1 Small Business Innovation Research (SBIR) grant by the Department of Defense to develop a next-generation adenovirus vaccine (see attached press release). This grant will fund proof-of-concept development including working virus bank generation for proteins expressed by adenovirus types 4 and 7 and demonstration of protein expression. We are in discussions for Phase 2/3 SBIR support.

We are also in the final stages of negotiating a stockpile contract with BARDA that will support product development of vaccine to combat influenza viruses of pandemic interest and the manufacturing of such vaccines.

We have submitted several grants to BARDA, National Institute of Allergy and Infectious Diseases (NIAID) and the Gates Foundation to fund new and existing vaccine development programs. These include programs for:

- FluNhance™ (recombinant neuraminidase (NA)-supplemented influenza vaccine) Submitted to BARDA
- Development of a recombinant human rabies vaccine Submitted to NIAID

- Micro-patch delivery of influenza vaccine Submitted to BARDA
- Vaccine production platform innovations to drive down costs Submitted to the Gates Foundation

Collaborations: We received a milestone payment upon regulatory approval of Flublok in Mexico and are preparing to ship the first Flublok doses for market introduction.

We expanded our collaboration with Pfizer this fall and entered into a new Services Agreement. Under the terms of the agreement, we are working with Pfizer to make early stage material for vaccine development. Pfizer has also agreed to renew their research license for our SF+ cell line with a commercial license option for one indication for a second year.

Our Research Antigens business, whereby we sell a variety of purified proteins and a limited number of antibodies for research purposes, continues to provide a profitable revenue stream. The majority of our customers purchase influenza and HIV antigens, involving a mix of in-stock and custom-produced proteins. Our customers comment that they appreciate the high quality of our proteins that are full length, functional and non-tagged. To view a list of our current offerings, please see http://proteinsciences.com/Res.htm.

Financial Results: For the nine months ended September 30, 2015 revenues increased 21% to \$27.6 million from \$22.8 million in 2014. This increase reflects an increase in the contribution from our BARDA contract that accounted for approximately 75% of revenues, up from 68% in the comparable period in 2014 primarily as a result of the initiation of two large clinical trials that are funded by BARDA. Product sales increased 80% to \$4.1 million but our Collaborative Agreements and Technology Licenses that together accounted for 10% of revenues were down 4% and 77%, respectively, to \$2 million and \$621,000 respectively. As a reminder, revenues from Collaborative Agreements and Technology Licenses are based on success in product development by our customers and, therefore, significantly increase or decrease on a quarterly basis. Operating expenses increased by 59% to \$29.6 million from \$18.6 million in 2014 primarily because of clinical trial expenses. We had an operating and net loss before tax expense and benefit of \$1.9 million, respectively, compared to an operating and net profit before tax expense and benefit of \$4.6 million in 2014. The increased loss results primarily from the seasonality of the flu business where almost all expenses are incurred in Qs 1, 2 and 3 and most revenues received in Q4 and the following Q1. Cash and receivables net of payables were \$1.1 million - \$8.2 million less than at the end of Q2 and \$14 million less than at the end of 2014 – again reflecting the seasonal nature of our flu business. Now that we are manufacturing for commercial sale the impact is much clearer than in previous years.

We continue to be highly dependent on support from our BARDA contract. We do expect to become less dependent on BARDA as we build Flublok sales and secure royalties from licenses, collaborative agreements and other government grants.

Cordially,

Manon M.J. Cox President & CEO

Manon Con

Daniel D. Adams Executive Chairman

Protein Sciences Corporation Balance Sheets (Unaudited)

	September 30, 2015		December 31, 2014	
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	\$	1,103,604	\$	5,818,164
Short term investment	*	3,208,133	,	3,630,057
BARDA funds receivable including unbilled of \$508,330				
and \$4,738,666, respectively		2,933,013		13,428,471
Accounts receivable including unbilled of \$189,434 and \$245,818,				
respectively and net of allowance for doubtful accounts of \$50,000				
and \$50,000, respectively		3,133,209		2,279,502
Inventory		9,414,344		2,207,079
Deferred tax asset		4,061,946		2,974,473
Other current assets		938,184		927,319
Total current assets		24,792,433		31,265,065
PROPERTY, PLANT AND EQUIPMENT Net		3,718,738		4,020,026
Long term deferred tax asset		4,960,017		4,960,017
Restricted cash		638,258		638,258
Other assets		507,553		350,859
TOTAL ASSETS	\$	34,616,998	\$	41,234,225
LIABILITIES AND STOCKHOLDERS' EQUITY CURRENT LIABILITIES:				
Accounts payable	\$	6,109,707	\$	7,627,970
Accrued expenses		2,287,856		4,904,104
Deferred revenue, current portion		499,980		1,076,578
Other current liabilities		147,290		147,290
Total current liabilities		9,044,833		13,755,942
LONG TERM LIABILITIES:				
Deferred revenue		592,171		956,555
Other liabilities		233,210		343,677
Total long term liabilities		825,380		1,300,232
TOTAL LIABILITIES		9,870,214		15,056,175
STOCKHOLDERS' EQUITY				
Common Stock, \$0.001 par value; 150,000,000 shares authorized;				
77,606,902 and 77,549,402 shares issued and outstanding at				
September 30, 2015 and December 31, 2014, respectively		77,607		77,549
Additional paid-in capital		63,811,669		63,519,642
Accumulated other comprehensive income, net of tax		146,168		641,955
Accumulated deficit		(39,288,659)		(38,061,095)
Total stockholders' equity		24,746,784		26,178,051
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	34,616,998	\$	41,234,225

Protein Sciences Corporation Statements of Operations (Unaudited)

Nine M	e Months Ending September 30,					
		2015		2014	Change	Revenue
REVENUES:						
BARDA contract	\$	20,786,342	\$	15,582,030	33%	75.1%
Collaborative agreements		2,091,741		2,176,988	-4%	7.6%
Technology licenses		621,983		2,756,814	-77%	2.2%
Product sales		4,169,390		2,311,189	80%	15.1%
Total revenues		27,669,455		22,827,021	21%	100.0%
OPERATING EXPENSES:						
Research and development		22,860,215		13,932,499	64%	82.6%
Cost of goods sold		1,940,701		808,579	140%	7.0%
General and administrative		4,851,436		3,931,426	23%	17.5%
Total operating expenses		29,652,352		18,672,504	59%	107.2%
INCOME FROM OPERATIONS		(1,982,896)		4,154,517	0%	-7.2%
(INCOME) OTHER EXPENSE:						
Interest expense		-		124	0%	0.0%
Interest income		(8,552)		(7,855)	9%	0.0%
Other income/expense		1,286		1,321		
Total other (income) expense		(7,266)		(6,409)	13%	0.0%
Net income before tax expense and benefit		(1,975,630)		4,160,926	0%	-7.1%
Tax (expense) benefit		748,065		(1,437,645)	0%	2.7%
Net Income	\$	(1,227,565)	\$	2,723,282	0%	-4.4%

Protein Sciences Corporation Statements of Cash Flow (Unaudited)

Nine Months Ending September 30,

	Nine Months	Months Ending September 30,		
		2015		2014
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net income	\$	(1,227,565)	\$	2,723,282
Adjustments to reconcile net income to net cash	•	(1,221,000)	Ψ	2,720,202
provided by operating activities:				
Realized gain on short term investment		_		_
Depreciation and amortization		409,937		1,211,858
Share-based compensation		277,709		246,906
Tax impact on unrealized loss on S/T investment		(73,863)		-
Excess tax benefit from stock compensation		-		_
Loss on disposal of assets		1,494		189
Deferred taxes		(1,087,473)		1,736,512
Changes in operating assets and liabilities:		•		
Inventory		(7,207,265)		(3,444,616)
Accounts receivable		(853,707)		1,134,983
BARDA funds receivable		10,495,458		2,083,163
Restricted cash		=		-
Other assets		(167,559)		69,004
Accounts payable and accrued expenses		(4,134,510)		(1,777,355)
Other liabilities		(110,467)		(402,215)
Deferred accounts		(940,982)		(762,567)
Net cash (used in) provided by operating activities	<u> </u>	(4,618,794)		2,819,144
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchase of investments		-		(118,753)
Purchases of property and equipment		(110,142)		(134,532)
Ned and for adding the seattle search the		(440.440)		(050,005)
Net cash (used in) investing activities		(110,142)		(253,285)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from exercise of stock options		14,376		3,206
Payments of capital lease obligations		14,570		5,200
r dymonic or depicer roads obligations				
Net cash (used in) provided by financing activities		14,376		3,206
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		,	-	
NET INCREASE IN CASH AND CASH EQUIVALENTS		(4,714,559)		2,569,065
		,		
CASH AND CASH EQUIVALENTS - Beginning of period		5,818,164		4,936,355
CASH AND CASH FOLINIAL ENTS. End of ported	•	1 102 605	¢	7 505 400
CASH AND CASH EQUIVALENTS - End of period	\$	1,103,605	\$	7,505,420
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION	ON.			
Cash paid for interest	\$	_	\$	124
Cash paid for taxes	\$	72,430	\$	106,582
Cacif paid for taxes	Ψ	. 2,-100	Ψ	100,002

Protein Sciences Corporation Statements of Comprehensive Income (Unaudited)

Nine Months Ending September 30,

	2015	2014		
Net Income	\$ (1,227,565)	2,723,282		
Other comprehensive income: Net change in unrealized gain in investments	\$ (495,787)	167,213		
Total Comprehensive Income	\$ (1,723,352)	\$ 2,890,495		





Protein Sciences and Connecticut Food Bank Partner to Offer Flublok® Influenza Vaccine to Those in Need

For Immediate Release

November 30, 2015

Contact:

Protein Sciences:
Rachael Felberbaum
Senior Director, Business Development
(203) 927-0752

Connecticut Food Bank:
Paul Shipman
Marketing & Communications Director
(203) 469-5000 ext. 309

Meriden and Wallingford, CT — Protein Sciences Corporation, makers of Flublok® Influenza Vaccine, and the Connecticut Food Bank announced a new initiative to support healthier families and stretch limited budgets to help keep food on the table.

Protein Sciences and the Connecticut Food Bank will coordinate a pilot program to offer Flublok vaccinations at food distributions during this holiday season. The pilot will pair the Connecticut Food Bank Mobile Pantry and Protein Sciences' Healthy Choices FastVax mobile flu vaccination clinic at community food distribution sites. The Connecticut Food Bank Mobile Pantry visits communities where there are transportation barriers and limited resources that make it difficult for low-income people to get the food they need. Protein Sciences earlier this year launched its Healthy Choices FastVax in collaboration with Hunter's Ambulance, Health Med Urgent Care, Health Mart Pharmacies and others. Putting the two services together in one location will help people get nutritious food and get Flublok vaccination at no cost. The first event will take place on Wednesday, December 2, 2015 at 10am at the Community Baptist Church at 143 Shelton Avenue in New Haven.

"Many of the same barriers that prevent people from getting the food they need also prevent access to healthcare," said Manon Cox, President and CEO of Protein Sciences. "We launched Healthy Choices FastVax to meet this need and promote health and wellbeing in our communities. This partnership with the Connecticut Food Bank Mobile Pantry is a natural extension and we hope will serve as a precedent for innovative ways to increase flu vaccination rates. The Food Bank is our new neighbor on Research Parkway and we are thrilled to work with them on this important public health initiative."

Connecticut Food Bank Interim CEO Paul O'Leary said the partnership supports good health and good nutrition in multiple ways. "Working with partners like Protein Sciences, we bring other resources to fight against hunger along with the nutritious food we provide at our Mobile

Pantry sites," O'Leary said. "Together we can help the people we serve reduce their risk of getting the flu and reduce the potential impact of illness on their budgets. We are grateful to Protein Sciences for recognizing a need and working with us to serve people in creative ways."

The Healthy Choices FastVax clinic will offer Flublok to adults 18 years and older. Insurance, including Medicare and Medicaid, will be accepted with no co-pay. Protein Sciences will provide vaccinations free of charge to those that do not have insurance. For more information about Flublok or the Connecticut Food Bank, please visit www.flublok.com or www.flublok.com or www.ctfoodbank.org.

About Protein Sciences

Protein Sciences specializes in vaccine development and protein production. Our mission is our inspiration: to save lives and improve health through the creation of innovative vaccines and biopharmaceuticals.

Flublok, the world's first recombinant protein-based vaccine for the prevention of seasonal influenza disease, was approved by FDA in January 2013. Flublok is the only flu vaccine made in a 100% egg-free system using modern cell culture technology, making it unnecessary to use an infectious influenza virus or antibiotics in manufacturing. Flublok is highly purified and does not contain any preservatives (e.g., thimerosal, a mercury derivative), egg proteins, gelatin or latex. In addition, Flublok contains three times more antigen than traditional flu vaccines (3x45mcg hemagglutinin protein versus 3x15mcg hemagglutinin protein)*. Flublok is a perfect copy of the virus coat and is not subject to the egg-adapted mutations associated with low vaccine effectiveness (see Skowronski et al. (2014) PLOS ONE 9(3), e92153).

Healthcare professionals wishing to order Flublok should contact one of the following distributors:

• FFF Enterprises: 800-843-7477 <u>www.myfluvaccine.com</u>

Cardinal Health: 866-677-4844 http://www.cardinal.com/us/en/SPD/Ordering

• McKesson: 877-MCK-4FLU <u>mms.mckesson.com</u>

• Henry Schein: 1-800-772-4346 www.henryschein.com

Learn more at <u>www.proteinsciences.com</u> and <u>www.flublok.com</u>.

About the Connecticut Food Bank

The Connecticut Food Bank is the state's non-profit leader in the fight against hunger and the largest provider of charitable food donations. Some 700 partners and programs depend on the Connecticut Food Bank as a lifeline to nutritious food for the communities they serve. The Connecticut Food Bank partnered last year with retailers, donors, volunteers and growers to provide enough food to prepare more than 18 million meals to more than 300,000 people across 127 cities and towns in six Connecticut counties. Visit us on the web at www.ctfoodbank.org, like us on Facebook and follow <a href="mailto-getter-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-produced-state-

Flublok Safety Information

Flublok is approved for people 18 and older to prevent influenza disease. The most common side effect from Flublok is pain at the site of injection. Headache, fatigue or muscle ache may occur. Tell the doctor if you have ever experienced Guillain-Barré syndrome (severe muscle weakness) or have had a severe allergic reaction to any component of Flublok vaccine. Vaccination with Flublok may not protect all individuals. Clinical effectiveness in adults 50 and older is based on the immune response elicited by Flublok and not on demonstration of decreased influenza disease. Please see the complete Package Insert available at www.flublok.com or call 203-686-0800 for more information.

*Flublok demonstrated a higher antibody response to the A strains during 2 clinical trials in adults ≥50 years old. The B strain antibody response was comparable to traditional trivalent vaccines.



Flublok® Influenza Vaccine Approved in Mexico

For Immediate Release

November 18, 2015

Contact:

Courtney Goodwin Communications Associate Phone: (203) 686-0800 ext. 301

Meriden, CT — Protein Sciences Corporation, manufacturer of Flublok®, is pleased to announce that Laboratorios Liomont, S.A. de C.V. (Liomont), a leading Mexican pharmaceutical company and licensee of Flublok for the Mexican market, has obtained approval from the Mexican regulatory agency COFEPRIS for Flublok for the prevention of influenza in adults 18 and older. This is a landmark moment as Flublok is the first recombinant influenza vaccine to be available in Mexico, offering pure and effective protection against the flu. Other influenza vaccines are made using 70 year old egg-based technology that is subject to mutations. The Mexican authorities also approved a 1 year shelf life and the use of the Flublok trade name.

"We are very pleased with the rapid approval of Flublok in Mexico and the approval of the longer shelf life," said Manon Cox, President and CEO of Protein Sciences. "Recombinant technology is the only technology that can produce an influenza vaccine with the precision to exactly match circulating flu strains. We saw the benefit of this last year with a field study in 9,000 older adults that showed that Flublok protected people against the flu better than a traditional, egg-based flu vaccine – Flublok recipients were over 50% less likely to become infected with the mismatched H3N2 influenza strain that was the predominant circulating strain last season. In addition, Mexico will now also be a nation better prepared in the event of a pandemic as Flublok is expected to be available within 8-12 weeks post declaration of a pandemic."

The rapid approval was the result of a strong team effort among many members of the Protein Sciences team, the National Autonomous University of Mexico and Liomont. Representatives from all three institutions will be present at a press conference today in Mexico City celebrating the approval.

Alfredo Rimoch, General Manager of Liomont, said, "For over 75 years we have been committed to the innovation and development of therapies to help relieve human suffering. Flublok's new technology for influenza vaccination is our gateway to the field of biotech drugs and marks the start-up of our new Life Sciences division."

Click <u>here</u> to read more about the licensing agreement between Protein Sciences and Liomont.

About Protein Sciences

Protein Sciences specializes in vaccine development and protein production. Our mission is our inspiration: to save lives and improve health through the creation of innovative vaccines and biopharmaceuticals.

Flublok, the world's first recombinant protein-based vaccine for the prevention of seasonal influenza disease, was approved by FDA in January 2013. Flublok is the only flu vaccine made in a 100% egg-free system using modern cell culture technology, making it unnecessary to use an infectious influenza virus or antibiotics in manufacturing. Flublok is highly purified and does not contain any preservatives (e.g., thimerosal, a mercury derivative), egg proteins, gelatin or latex. In addition, Flublok contains three times more antigen than traditional flu vaccines (3x45mcg hemagglutinin protein versus 3x15mcg hemagglutinin protein)*. Flublok is a perfect copy of the virus coat and is not subject to the egg-adapted mutations associated with low vaccine effectiveness (see Skowronski et al. (2014) PLOS ONE 9(3), e92153).

Healthcare professionals wishing to order Flublok should contact one of the following distributors:

• FFF Enterprises: 800-843-7477 <u>www.myfluvaccine.com</u>

• Cardinal Health: 866-677-4844 http://www.cardinal.com/us/en/SPD/Ordering

McKesson: 877-MCK-4FLU <u>mms.mckesson.com</u>

• Henry Schein: 1-800-772-4346 <u>www.henryschein.com</u>

Learn more at www.proteinsciences.com and www.flublok.com.

About Liomont

Liomont is a 100% Mexican pharmaceutical company established in 1938, ranked number 8 in the national pharmaceutical market in units and 16 in value in 2014, with high quality prescription and OTC products. It has one of the most dynamic growth rates in the market. Liomont has a capacity of more than 120 million units per year in a high tech facility considered to be one of the most modern in Latin America. It has approximately 1500 employees of which more than half are medical sales reps with the aim of creating a solid and collaborative team. In addition to marketing activities, Liomont has the social mission to be a source of employment, training and development of its people to ensure a better quality of life. The Company has received the Socially Responsible Company Award for 10 continuous years due to its outstanding commitment to society. Other public and private institutions have also recognized several initiatives in business and ecology among others.

Flublok Safety Information

Flublok is approved for people 18 and older to prevent influenza disease. The most common side effect from Flublok is pain at the site of injection. Headache, fatigue or muscle ache may occur. Tell the doctor if you have ever experienced Guillain-Barré syndrome (severe muscle weakness) or have had a severe allergic reaction to any component of Flublok vaccine. Vaccination with Flublok may not protect all individuals. Clinical effectiveness in adults 50 and older is based on the immune response elicited by Flublok and not on demonstration of

decreased influenza disease. Please see the complete Package Insert available at www.flublok.com or call 203-686-0800 for more information.

*Flublok demonstrated a higher antibody response to the A strains during 2 clinical trials in adults ≥50 years old. The B strain antibody response was comparable to traditional trivalent vaccines.



Protein Sciences Awarded a Small Business Innovation Research Grant for the Development of a Novel Adenovirus Vaccine

For Immediate Release

November 12, 2015

Contact:

Courtney Goodwin Communications Associate Phone: (203) 686-0800 ext. 301

Meriden, CT — Protein Sciences Corporation, makers of Flublok® Influenza Vaccine, announced today that they have been awarded a Phase I Small Business Innovation Research (SBIR) Grant by the U.S. Department of Defense (DoD) for the development of a next generation adenovirus vaccine. Adenovirus infection is a major cause of acute respiratory disease in U.S. military recruits. The existing vaccine is effective but contains live wild type adenovirus that is capable of being transmitted to others. Under this award, Protein Sciences will apply its proprietary BEVS platform technology to develop a protein-based vaccine designed to protect against the two major types of adenovirus, Types 4 and 7, without using live adenovirus.

"We are very pleased to be working with the DoD to develop a modern adenovirus vaccine," said Indresh Srivastava, Vice President of Process and Analytical Development at Protein Sciences and Principal Investigator of the grant. "Adenovirus affects a large population every year, and our BEVS platform is well suited to address the challenges associated with the existing vaccine. This program is yet another way that we are continuously working to save lives and improve health."

Adenoviruses are common causes of respiratory illness. The incubation period is typically 4-5 days after which people who become infected experience high fever, cough, nasal congestion, headache and chest pain typically lasting 3-10 days.

About Protein Sciences

Protein Sciences specializes in vaccine development and protein production. Our mission is our inspiration: to save lives and improve health through the creation of innovative vaccines and biopharmaceuticals.

Flublok, the world's first recombinant protein-based vaccine for the prevention of seasonal influenza disease, was approved by FDA in January 2013. Flublok is the only flu vaccine made in a 100% egg-free system using modern cell culture technology, making it unnecessary to use an infectious influenza virus or antibiotics in manufacturing. Flublok is highly purified and does not contain any preservatives (e.g., thimerosal, a mercury derivative), egg proteins, gelatin or latex. In addition, Flublok contains three times more antigen than traditional flu vaccines

(3x45mcg hemagglutinin protein versus 3x15mcg hemagglutinin protein)*. Flublok is a perfect copy of the virus coat and is not subject to the egg-adapted mutations associated with low vaccine effectiveness (see Skowronski et al. (2014) PLOS ONE 9(3), e92153).

Healthcare professionals wishing to order Flublok should contact one of the following distributors:

• FFF Enterprises: 800-843-7477 <u>www.myfluvaccine.com</u>

Cardinal Health: 866-677-4844 http://www.cardinal.com/us/en/SPD/Ordering

• McKesson: 877-MCK-4FLU mms.mckesson.com

• Henry Schein: 1-800-772-4346 <u>www.henryschein.com</u>

Learn more at www.proteinsciences.com and www.flublok.com.

Flublok Safety Information

Flublok is approved for people 18 and older to prevent influenza disease. The most common side effect from Flublok is pain at the site of injection. Headache, fatigue or muscle ache may occur. Tell the doctor if you have ever experienced Guillain-Barré syndrome (severe muscle weakness) or have had a severe allergic reaction to any component of Flublok vaccine. Vaccination with Flublok may not protect all individuals. Clinical effectiveness in adults 50 and older is based on the immune response elicited by Flublok and not on demonstration of decreased influenza disease. Please see the complete Package Insert available at www.flublok.com or call 203-686-0800 for more information.

*Flublok demonstrated a higher antibody response to the A strains during 2 clinical trials in adults ≥50 years old. The B strain antibody response was comparable to traditional trivalent vaccines.



Protein Sciences President and CEO Manon Cox Elected as 2015 Fellow of the International Society for Vaccines

For Immediate Release

October 29, 2015

Contact:

Courtney Goodwin Communications Associate Phone: (203) 686-0800 ext. 301

Meriden, CT — Protein Sciences Corporation, the makers of Flublok® Influenza Vaccine, announced today that Dr. Manon Cox, President and CEO, was elected as a 2015 Fellow of the International Society of Vaccines (ISV). The ISV is an esteemed organization dedicated to the development, advancement and use of vaccines to prevent and control disease. ISV Fellows represent a distinguished pool of scientists, doctors and professionals that have contributed significantly to this field. Past ISV Fellows include Sabin Gold Medal and Fleming Award Winner Dr. Stanley Plotkin, internationally renowned microbiologist Dr. Peter Palese, and industry leaders like Drs. Emilio A. Emini and Rino Rappuoli.

"I am deeply honored to be elected into this prestigious circle," said Dr. Cox. "Flublok is being recognized as a major advance and this appointment demonstrates that the vaccine industry recognizes that innovation in vaccines is much needed."

Dr. Indresh Srivastava, Vice President of Process and Analytical Development at Protein Sciences, has also been nominated to serve on the Executive Board for the ISV. Dr. Srivastava is a leading biochemist and vaccinologist and has been involved in the development of vaccines against malaria, HIV, SARS, HepC, Men B, West Nile and influenza in both academic and industrial settings for the last 25 years.

For more information about Protein Sciences, Flublok, and the ISV, please visit www.flublok.com and www.isv-online.org.

About Protein Sciences

Protein Sciences specializes in vaccine development and protein production. Our mission is our inspiration: to save lives and improve health through the creation of innovative vaccines and biopharmaceuticals.

Flublok, the world's first recombinant protein-based vaccine for the prevention of seasonal influenza disease, was approved by FDA in January 2013. Flublok is the only flu vaccine made in a 100% egg-free system using modern cell culture technology, making it unnecessary to use an infectious influenza virus or antibiotics in manufacturing. Flublok is highly purified and does not

contain any preservatives (e.g., thimerosal, a mercury derivative), egg proteins, gelatin or latex. In addition, Flublok contains three times more antigen than traditional flu vaccines (3x45mcg hemagglutinin protein versus 3x15mcg hemagglutinin protein)*. Flublok is a perfect copy of the virus coat and is not subject to the egg-adapted mutations associated with low vaccine effectiveness (see Skowronski et al. (2014) PLOS ONE 9(3), e92153).

Healthcare professionals wishing to order Flublok should contact one of the following distributors:

• FFF Enterprises: 800-843-7477 www.myfluvaccine.com

• Cardinal Health: 866-677-4844 http://www.cardinal.com/us/en/SPD/Ordering

• McKesson: 877-MCK-4FLU mms.mckesson.com

• Henry Schein: 1-800-772-4346 www.henryschein.com

Learn more at www.proteinsciences.com and www.flublok.com.

Flublok Safety Information

Flublok is approved for people 18 and older to prevent influenza disease. The most common side effect from Flublok is pain at the site of injection. Headache, fatigue or muscle ache may occur. Tell the doctor if you have ever experienced Guillain-Barré syndrome (severe muscle weakness) or have had a severe allergic reaction to any component of Flublok vaccine. Vaccination with Flublok may not protect all individuals. Clinical effectiveness in adults 50 and older is based on the immune response elicited by Flublok and not on demonstration of decreased influenza disease. Please see the complete Package Insert available at www.flublok.com or call 203-686-0800 for more information.

*Flublok demonstrated a higher antibody response to the A strains during 2 clinical trials in adults ≥50 years old. The B strain antibody response was comparable to traditional trivalent vaccines.



Protein Sciences Launches New Website for Flublok® Influenza Vaccine

For Immediate Release

October 15, 2015

Contact:

Courtney Goodwin Communications Associate Phone: (203) 686-0800 ext. 301

Meriden, CT — Protein Sciences Corporation launched its new website for Flublok Influenza Vaccine, your pure choice in flu vaccines. The website, which can be accessed at www.flublok.com, has several new user-friendly features, including:

- The Flublok Finder allowing you to input a zip code to find the nearest locations offering the Flublok;
- A fun 3D animated video explains how Flublok differs from traditional flu vaccines;
- Downloadable resources for healthcare professionals detailing the clinical benefits of Flublok and clinical study results;
- Integrated social media
- Also, soon to come: photographs of Flublok and video footage available for download.

"We are very excited to announce the launch of our new website," said Manon Cox, President and CEO. "The new site reflects an important message - that people have a <u>choice</u> in flu vaccines. Flublok is the PURE choice both because of its purity (completely free of egg protein, preservatives, antibiotics, gelatin, latex, gluten, formaldehyde and influenza virus) and its efficacy. We expect that our new interactive website will stimulate conversation and prompt people to ask for Flublok."

Flublok is approved for all adults 18 years and older and is available nationwide at Target pharmacies, many pharmacies in large grocery stores, and Passport Health clinics, and locally at many independent pharmacies. Flublok is fully covered by most insurance plans – it has a unique reimbursement code because of its advantages compared to traditional flu vaccines and because it is an important preventative medicine.

For more information about Flublok, where to get it, and to see the newly designed website, visit www.flublok.com.

About Protein Sciences

Protein Sciences specializes in vaccine development and protein production. Our mission is our inspiration: to save lives and improve health through the creation of innovative vaccines and biopharmaceuticals.

Flublok, the world's first recombinant protein-based vaccine for the prevention of seasonal influenza disease, was approved by FDA in January 2013. Flublok is the only flu vaccine made in a 100% egg-free system using modern cell culture technology, making it unnecessary to use an infectious influenza virus or antibiotics in manufacturing. Flublok is highly purified and does not contain any preservatives (e.g., thimerosal, a mercury derivative), egg proteins, gelatin or latex. In addition, Flublok contains three times more antigen than traditional flu vaccines (3x45mcg hemagglutinin protein versus 3x15mcg hemagglutinin protein)*. Flublok is a perfect copy of the virus coat and is not subject to the egg-adapted mutations associated with low vaccine effectiveness (see Skowronski et al. (2014) PLOS ONE 9(3), e92153).

Healthcare professionals wishing to order Flublok should contact one of the following distributors:

• FFF Enterprises: 800-843-7477 <u>www.myfluvaccine.com</u>

• Cardinal Health: 866-677-4844 http://www.cardinal.com/us/en/SPD/Ordering

• McKesson: 877-MCK-4FLU mms.mckesson.com

• Henry Schein: 1-800-772-4346 <u>www.henryschein.com</u>

Learn more at <u>www.proteinsciences.com</u> and <u>www.flublok.com</u>.

Flublok Safety Information

Flublok is approved for people 18 and older to prevent influenza disease. The most common side effect from Flublok is pain at the site of injection. Headache, fatigue or muscle ache may occur. Tell the doctor if you have ever experienced Guillain-Barré syndrome (severe muscle weakness) or have had a severe allergic reaction to any component of Flublok vaccine. Vaccination with Flublok may not protect all individuals. Clinical effectiveness in adults 50 and older is based on the immune response elicited by Flublok and not on demonstration of decreased influenza disease. Please see the complete Package Insert available at www.flublok.com or call 203-686-0800 for more information.

*Flublok demonstrated a higher antibody response to the A strains during 2 clinical trials in adults ≥50 years old. The B strain antibody response was comparable to traditional trivalent vaccines.