



BioPurification Quarterly[™]

A Newsletter by ProMetic BioSciences
Q4 2009

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Greetings!

Welcome to the fourth quarter 2009 edition of ProMetic BioSciences Ltd's ("PBL") BioPurification Quarterly[™] newsletter! We hope that, by reading this newsletter, you will be better informed of what's new at PBL. In each newsletter you'll find information on...

- New Products
- PBL Press Releases
- Special Offers
- Upcoming Events
- New Applications

Thanks again and we hope you enjoy the newsletter!
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→ ProMetic Signs Long-Term Supply Agreement with Major Global Pharmaceutical Company

Prometic recently (September 24, 2009) announced the signing of a long-term supply agreement with a major global pharmaceutical company for supply of a commercially available Mimetic Ligand[™] affinity adsorbent developed and manufactured by ProMetic Biosciences Ltd. The agreement is for an initial 5-year term and includes customary provisions for supply of a purification component used by ProMetic's customer for the manufacture of a biopharmaceutical product currently in Phase III clinical trials and about to undergo manufacturing scale-up in anticipation of regulatory approval and market launch within the timeframe of the agreement.



This latest application for a Mimetic Ligand[™] product is anticipated to require large volumes of Mimetic Ligand[™]

[Glycoprotein Removal](#)

[Pathogen Reduction](#)

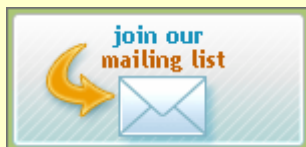
[Nucleic Acid Purification](#)

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Development](#)

[Prion Removal and
Detection Technologies](#)

[PBL Online Shop](#)

Join our mailing list to be notified of special offers from ProMetic BioSciences Ltd!



Upcoming Events

IBC Biopharmaceutical Development & Production Week

Date: March 1-5, 2010
Venue: La Costa Resort & Spa, Carlsbad CA
More about this event

PrP-CANADA 2010 - Canada's Prion Research Conference

Date: March 8-10, 2010
Venue: The Westin Ottawa, Ottawa, Ontario, Canada

BioProcess International European Conference

adsorbent and is expected to provide recurring revenues from orders placed over the duration of the Agreement.

According to Dr. Steve Burton, Chief Executive Officer of ProMetic Biosciences Ltd: "The signing of this agreement is very significant as it confirms the Company as a leading supplier of bioseparation products and technology to the biopharmaceutical industry. To be selected as a key supplier to big pharma for a very large-scale manufacturing process underscores the quality and performance of our products and the confidence of ProMetic's clients in our ability to meet their future needs".

[Click here to view the full press release](#)

[Click here to learn more about Mimetic Ligands™](#)

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→ SaBTO recommends use of P-Capt® prion reduction filter to protect children from vCJD blood transmission

On November 20, 2009 ProMetic Life Sciences Inc. and MacoPharma SA announce that the Advisory Committee on the Safety of Blood, Tissues and Organs ("SaBTO"), an independent Committee that advises the UK Department of Health, has recommended the adoption of the P-Capt® prion reduction filter to pre-treat red blood cells destined for children born since 1 January 1996. The filter, which 'cleans' blood prior to use, removes the prion responsible for variant Creutzfeldt-Jakob disease ("vCJD"). The Committee also indicated that the requirement for prion filtration should be reviewed in the event that further data on vCJD prevalence or filter efficacy becomes available.



The SaBTO recommendation is subject to the satisfactory completion of the PRISM study, a multi-centre clinical trial initiated in 2007 to evaluate the safety of P-Capt® filtered red cells. The 540 patient study is scheduled to conclude early next year. PRISM is the third clinical study conducted on P-Capt® filtered red cells and follows two separate human trials conducted by ProMetic / MacoPharma and the Irish Blood Transfusion Service. Both of these studies demonstrated the P-Capt® filter successfully met all safety requirements with no adverse events.

and Exhibition

Date: May 19-20, 2010
Venue: Reed Messe Wien,
Vienna, Austria

Save 10% on HIC Adsorbents



For a limited time only PBL is offering 10% off all website orders for our HIC adsorbents exclusive to our Newsletter readers!

In order to take advantage of this opportunity an order must be placed with a valid credit card via PBL's new online shop anytime between October 1st and December 15th, 2009.

This coupon is transferable! Please click "send to a colleague" to share this coupon with a colleague.

[Click here to take advantage of this limited time offer!](#)

Offer expires December 15th, 2009

Are Glycoprotein Impurities a Problem in Your Process?

"The SaBTO recommendation states that there is 'now sufficient evidence that P-Capt® reduces infectivity' and as such it is an important independent endorsement of the efficacy of the filter" commented Ms. Iwona Walicka, Project Manager of MacoPharma, which manufactures and distributes the filter. Ms. Walicka added: "1.8 million blood units are donated in England each year and yet we have no idea how many blood donors are incubating the vCJD prion, which can lie dormant for decades. What we do know for sure is that vCJD is a devastating disease for which there is no cure and that it can be transmitted by transfusion of infected blood/blood products. P-Capt® has been extensively and independently tested for three years: it works (99.9% or greater of reduction efficacy), it's safe and it's available now. Its adoption makes sense: because everyone has a right to safe blood."


The P-Capt® filter is the only approved product proven to be effective for the removal of endogenous blood-borne prion infectivity from RBC prior to transfusion. Red blood cells are passed through the filter under gravity and a highly specific affinity adsorbent material captures and removes any vCJD prion protein.

P-Capt® is a single-use sterile device which was awarded CE mark approval in September 2006 and has been available commercially since this time for RBC filtration. P-Capt® has been evaluated extensively by the UK Blood Services (including the National Blood Service, the Welsh Blood Service, and the Scottish National Blood Transfusion Service and the Northern Ireland National Blood Service), the Irish National Blood Transfusion Service and the Health Protection Agency since production of the first batches in 2006 and to date has achieved all of the required performance and safety requirements and met all bench marks.

The prion binding material used in the filter was developed by Pathogen Removal and Diagnostic Technologies Inc. ("PRDT"), a commercial joint venture between ProMetic, the American Red Cross and leading U.S. academics. The P-Capt® filter incorporating the prion-specific affinity resin supplied by ProMetic to MacoPharma is manufactured under license by MacoPharma. ProMetic's affinity resins have also been applied successfully to the removal of prions from other blood-derived products such as viral inactivated plasma.

[Click here to view the full press release](#)
[Click here to learn more about PRDT and the P-Capt® filter](#)



 **More Customers Now Shop On-Line for PBL's Comprehensive Range of Chromatography Adsorbents**



Aminophenylboronate P6XL is a synthetic affinity adsorbent particularly well suited to the purification of glycoproteins, or the removal of glycoprotein and carbohydrate impurities from non-glycosylated molecules (including glycoprotein antigens).

Aminophenylboronate adsorbents are highly stable, resistant to concentrated sodium hydroxide, exhibit negligible ligand leakage and are capable of maintaining their high performance over a very large number of process cycles, even after prolonged storage in sodium hydroxide.

[Click here for more information on Aminophenylboronate P6XL](#)

[Click here to purchase a sample of Aminophenylboronate P6XL](#)

PBL's Custom Adsorbent Development Program

Since the successful launch of our dedicated new PBL website earlier this year, the number of customers taking advantage of our secure on-line shopping facility (inc. American Express®) has continued to grow beyond expectation.



The on-line Shop service allows our customers to search and access PBL's comprehensive range of standard off-the-shelf adsorbents in a more simple, timely and cost-efficient manner. Indeed, some customers have gone on to benefit from special pricing for on-line ordering of featured products e.g. current offer of Hydrophobic Interaction adsorbents*.

To access our on-line shopping facility, please visit us at: www.prometicbiosciences.com/shop/

We also invite you to visit the entire PBL website to learn more about how PBL's existing products can serve the needs of your development application, or indeed, existing manufacturing process - in the Applications & Products section. From here, quickly link to the appropriate product range in the Shop section. For support, follow links, or scroll, to download the relevant supporting technical documentation from our Literature section - a comprehensive scientific library (which catalogues Product Brochures; Application Notes; User Manuals; MSDS; numerous scientific publications and references - as well as previous editions of this quarterly newsletter!).

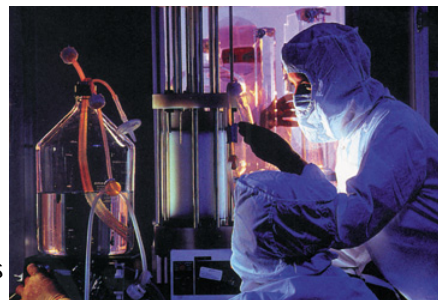
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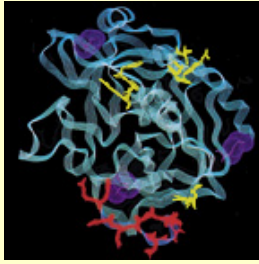


* Offer on HIC adsorbents ends 15th December

→ A Synthetic Affinity Adsorbent that Selectively Binds Albumin Fusion Proteins

The use of biopharmaceuticals is often constrained by a number of challenges including poor bioavailability and lack of efficacy over a prolonged period due short protein half-life *in vivo*. This means that the drug has to be administered at a





Want to develop an affinity capture step for your difficult to purify protein?

PBL's Custom Adsorbent Development Program enables the development of Mimetic Ligand™ adsorbents tailored to suit almost any target biomolecule by use of Intelligent Combinatorial Chemistry® which comprises automated synthesis and screening of ligand libraries against the target biomolecule of interest. These programs are conducted by PBL in-house and we work closely with the sponsor throughout.

[Click here for more information on this program](#)

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frequent high level of dosing, which may lead to undesired side effects and limit the therapeutic benefits.

Albumin fusion technology has been developed by Novozymes Biopharma to address some of these challenges. Albumin is benign carrier protein found in concentrations in excess of 30g/L in plasma, and has a half-life of twenty days. Albumin fusion technology uses molecular fusion of albumin to protein drug candidates by means of a contiguous cDNA for the target peptide/protein drug with DNA encoding albumin to provide a single hybrid protein. This technology is used in a range of protein expression systems including yeast and animal cells allowing stable expression of an extensive range of protein therapeutics. A major advantage in the clinical use of these drugs is extended circulatory half life and improved bioavailability.

Additional advantage offered by this technology is the ability to produce such pharmaceuticals at a relatively low cost due the lower purification costs as result of the use of synthetic affinity adsorbent for capture and purification of resulting biopharmaceuticals. Mimetic Blue® SA P6XL affinity adsorbent utilizes an optimised ligand designed for highly selective binding to the albumin molecule which was obtained by using the 'analogue synthesis' approach for ligand optimisation of an existing protein binding ligand. The optimised ligand is immobilised on to PuraBead® 6XL, a near monodisperse beaded 6% cross-linked agarose which offers excellent flow properties and high protein binding capacities. This adsorbent is in use for commercial purification of a number of albumin fusion proteins.

[Click here to learn more about Mimetic Blue® SA P6XL](#)
[Click here to purchase a sample of Mimetic Blue® SA P6XL](#)

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ProMetic BioSciences Ltd is a private company limited by shares, incorporated in the Isle of Man with registered number 034251C. The company is also registered as a foreign company at Companies House in the UK, with registration number FC027128. ProMetic BioSciences UK is the branch name of ProMetic BioSciences Ltd, and is registered as a Branch in England & Wales with registration number BR009067. The registered office of ProMetic BioSciences UK and ProMetic BioSciences Ltd is Freeport, Ballasalla, Isle of Man, IM9 2AP, British Isles. The liability of the members of ProMetic BioSciences Ltd is limited.

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