

3 December 2013

FLEXISEQ Gel Launched in UK: Pioneering joint pain treatment supports leading Arthritis charity

Pro Bono Bio[®], the global leader in nano-physical healthcare products, announces the UK Charity launch of FLEXISEQ[™], the innovative drug-free, safe treatment for joint pain associated with osteoarthritis¹ (OA). FLEXISEQ's proven efficacy comes with significant advantages as the product has no contra-indications, contains no drugs so cannot cause drug-to-drug interactions, and with over 6 million doses administered since launch there have been no reported systemic side effects.

FLEXISEQ is already successfully sold in the early pilot markets of Austria, Germany, Ireland, Malaysia and Singapore. Earlier this year, FLEXISEQ won the Innovation Award 2013 from the Federal Association of German Pharmacists. In June, FLEXISEQ launched in Ireland and became the fastest growing over-the-counter product that pharmacies there had seen in recent times.

UK Charity Launch

John Mayo, Chairman and Chief Executive of Pro Bono Bio said "I am proud to bring the world's first clinically proven nano-physical product for pain relief to the UK. For the UK Charity launch period, FLEXISEQ is exclusively available online via the Arthritis Research UK website www.arthritisresearchUK.org/Flexiseq and in 500 selected branches of LloydsPharmacy across the UK. This restricted launch is a unique way for us to provide a contribution to medical research by supplying Arthritis Research UK at a special price which allows them to sell to the public at the reduced price of £16.80 per pack and generate funds for the charity. LloydsPharmacy have also agreed to make a £1 donation to Arthritis Research UK for every tube they sell during this UK Charity launch period. We hope to contribute over £500,000 to Arthritis Research UK in this way and would like all sufferers of joint pain (or their friends and relatives) to order early for Christmas delivery and help Arthritis Research UK."

The UK Patient Need

Dr Liam O'Toole, Chief Executive, Arthritis Research UK said, "We know that nearly nine million people in the UK have sought treatment for osteoarthritis, which is a painful and extremely debilitating condition. Current approaches to treating this chronic pain are inadequate, and we are interested in the potential of this new drug-free approach. We very much look forward to making FLEXISEQ available to the public on our website and hearing our patients' feedback. We welcome the contribution Pro Bono Bio and LloydsPharmacy are making towards our work as we fight to find new approaches to treating pain in osteoarthritis".

Commenting on the UK launch of FLEXISEQ, Nitin Makadia, LloydsPharmacy pain expert and pharmacist, said: "Pain management is one of our key areas of focus and we recognise that osteoarthritis is a widespread issue affecting an estimated 8.75 million people aged 45 years and over in the UK. Along with support we also believe it is important to offer our patients the best and most innovative healthcare products to help them manage their health. We are excited to be working with the FLEXISEQ team to bring this pioneering new product to our patients."

More information is available for patients from a dedicated Flexiseq info line on 0800 098 7011.

Mode of Action

FLEXISEQ is different as it does not contain an active pharmaceutical ingredient but rather works through a patented physical mode of action because it increases the level of bio-lubrication in the affected joint. One of the features of OA is a depletion in the level of phospholipids in the joint, normally found in the liquid around the cartilage. These

phospholipids play an important role in lubricating the joint and, as a consequence, their deficiency contributes to the pain, stiffness and loss of function inherent in OA. FLEXISEQ targets this root cause of osteoarthritis pain.

FLEXISEQ contains patented phospholipid vesicles that are formulated using Sequeosome Technology® to be ultra-deformable, and have been shown to penetrate into the joint, after topical application and being allowed to dry, where they supplement the bio-lubrication in the synovial space. As there is no active pharmaceutical ingredient and as FLEXISEQ has a physical mode of action, it is registered as a medical device under the appropriate European legislation and therefore does not require a prescription.

FLEXISEQ: Clinical Evidence

Research from several clinical studies² proved that FLEXISEQ effectively improves joint mobility and eases pain for those suffering from osteoarthritis. One study of 1,300 patients, published in *Rheumatology*, found FLEXISEQ is as good for pain relief as a commonly prescribed drug, celecoxib, but with a much better safety profile.

Dr John Dickson, founder of the Primary Care Rheumatology Society and co-author of the paper, commented: “It is well recognised that effectively managing chronic pain, particularly in patients with other conditions and risk factors, is a massive challenge that GPs and patients face on a daily basis. I am delighted that FLEXISEQ is being launched in the UK. This topical treatment is drug-free and seems to have an excellent safety profile. In this study, FLEXISEQ was shown to be as effective as the routinely used oral NSAID, celecoxib, in reducing both pain and joint stiffness. FLEXISEQ can be used alongside a patient’s oral medication. I understand that in markets where FLEXISEQ is already available it has been welcomed by healthcare professionals, patients and patient groups alike. There is already a lot of interest in the UK about this exciting new treatment.”

Prof Philip G Conaghan of the University of Leeds, lead author of the *Rheumatology* paper, said: “Osteoarthritis is a common condition, especially in the growing number of elderly people. It causes chronic pain and stiffness which adversely affects patients’ lives. The need for new treatment options is well recognised as existing treatments don’t always work and many can cause serious side effects. Many OA patients are elderly and have additional health conditions that mean they are especially at risk of these side effects. Safety is therefore a key concern for new therapies and patients and healthcare professionals would welcome new treatment options which are effective and without such safety concerns.”

Michael Earl, Chief Operating Officer of Pro Bono Bio said, “The proven physical mode of action and the lack of an active pharmaceutical ingredient give FLEXISEQ the best of both worlds: it works and it’s safe. The lack of systemic side effects that have been recorded when drugs are used chronically, such as gastrointestinal bleeding, kidney failure, heart attack and stroke, together with a lack of drug interactions makes FLEXISEQ a particularly suitable option for many OA patients, who are elderly and may be suffering from other conditions and taking other medications, which complicate the choice of therapy for their painful joints. The problems with using older medications such as the non-steroidal anti-inflammatory drugs in these patients are becoming increasingly well recognised following the research published in the *Lancet*, earlier this year, and so we believe that FLEXISEQ is a very valuable addition to the treatment options available.”

Commercial Launch

At the end of January 2014, FLEXISEQ will have a full commercial launch and will be available via all LloydsPharmacy stores and all other good pharmacies as production catches up with anticipated demand from the UK’s 8.75 million sufferers of osteoarthritis. It is anticipated that Arthritis Research UK will continue to sell FLEXISEQ from their website to continue raising money for important medical research.

References and footnotes:

¹In clinical trials there were no health issues associated with long term use of FLEXISEQ™. Sequeosome™ constituents that lubricate the joints are designated as GRAS (Generally Recognised As Safe) by the US FDA.

²Conaghan P, et al Curr Med Res Opin 2013;1-13 November 2013

Conaghan P, Dickson J, Bolten W, Cevc G, Rother M. Rheumatology 2013 Jul; 52(7):1303-12

Rother M, Conaghan PG. J Rheumatology 2013 2013; 40:1742-48

³Coxib and Traditional NSAID Trialists' (CNT) Collaboration. Vascular and upper gastrointestinal effects of non-steroidal anti-inflammatory drugs: meta-analyses of individual participant data from randomised trials. Lancet 2013; pii: Q5 S0140-6736(13)60900-9

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Sequessome Technology[®]

FLEXISEQ employs Pro Bono Bio's patented Sequessome Technology rather than an active pharmaceutical ingredient to target a root cause of the disease, relieving pain with comparable efficacy to celecoxib, a leading prescription drug used for treating OA pain. Sequessome Technology utilises nanostructures called Sequessome[™] vesicles that cross the skin barrier after the gel's topical application and migrate through various tissues to the target joint. Once inside the joint, Sequessome vesicles accumulate on the damaged cartilage forming a lubricating layer.

This targeted, physical mode of action crucially means there are no drug-to-drug interactions with FLEXISEQ as it is not itself a drug and, as a result, it can be used by patients who may be taking a variety of medications for other diseases, without increasing their drug burden. FLEXISEQ is also a welcome option for patients considered 'at risk' from the more common side effects associated with NSAIDs for example, those with such conditions as high blood pressure, gastric disorders or asthma.

About Pro Bono Bio

Pro Bono Bio is an innovative healthcare and nano medical device company launched in 2011. Pro Bono Bio launched FLEXISEQ in Europe in 2012 and plans to launch two further new products for the treatment of inflammatory skin disorders in 2013/2014. These new products, ROSSOSEQ[®] and EXOSEQ[™], are based on Sequessome Technology, the same technology that powers FLEXISEQ. Pro Bono Bio expects these to launch in Ireland in January 2014.

Pro Bono Bio has ambitious growth targets that will allow it to support a unique humanitarian mission. In 2012, it started that mission by supporting elderly (less well off) pilgrims from West Africa on the Hajj to Mecca, alleviating the joint pain caused by long periods of walking and kneeling. The support for the less wealthy Hajj pilgrims has continued in 2013 in Asia. Our Charity launch is a further example of our support for this mission.

Arthritis Research UK

Arthritis Research UK is dedicated to leading the fight against arthritis and committed to being at the forefront of international efforts to develop new treatments. As a charity needing to raise over £40 million each year to fund our work, we welcome the contribution Pro Bono Bio and Lloyds are making towards our work as we fight to find new approaches to treating pain in osteoarthritis.

About LloydsPharmacy

LloydsPharmacy has over 1500 pharmacies across the UK. These are based predominantly in community and health centre locations. The company employs over 17,000 staff and dispenses over 150 million prescription items annually. The LloydsPharmacy pain service is free and no appointment is necessary. The pharmacist will discuss symptoms, medication and lifestyle to help reduce pain such as joint, arthritic and back pain. The pharmacist will help to set personal pain management goals which will include recommendations such as advising on moderate exercise or adjusting a medicines routine to improve sleep patterns.