

Archimedes Pharma Announces All Wales Medicines Strategy Group Recommendation of PecFent[®]▼ (fentanyl pectin nasal spray) for use within NHS Wales

Reading, England, 6 September 2011 – Archimedes Pharma UK Limited today announced that the All Wales Medicines Strategy Group (AWMSG) has recommended PecFent[®]▼ (fentanyl pectin nasal spray) as an option for use within National Health Service (NHS) Wales for the management of breakthrough pain in adults who are already receiving maintenance opioid therapy for chronic cancer pain. PecFent should only be considered as an option for the management of breakthrough cancer pain when immediate release oral opioids are either inadequate or unsuitable. PecFent may be suitable for shared care but should be initiated by, and remain under the supervision of a specialist physician experienced in the management of opioid therapy in cancer patients.

“We are pleased with the positive decision and recommendation by the AWMSG as it will provide healthcare professionals in NHS Wales with a new treatment option for the management of breakthrough pain in cancer patients,” said Andy Farrant, general manager, Archimedes Pharma UK. “Patients with this distressing condition need a rapid-acting treatment that they can rely on. We see the availability of PecFent in Wales as a step forward in the care of patients suffering with breakthrough pain in cancer.”

The AWMSG recommendation follows the acceptance of PecFent by the Scottish Medicines Consortium in January 2011. The AWMSG reviewed evidence of cost-utility as well as clinical data from three phase 3 studies involving more than 650 patients. In a placebo-controlled study, the sum of the pain intensity difference scores up to 30 minutes (SPID30; primary endpoint) was significantly greater for patients receiving PecFent compared with placebo.^{1,2} In addition, clinically meaningful pain relief occurred rapidly; as early as 5 minutes in one third of BTP episodes.^{1,2}

In a second study comparing PecFent to immediate release morphine sulphate (IRMS), PecFent had a significantly faster onset of action compared to IRMS and provided a significantly greater reduction in pain intensity than IRMS at 15 minutes (primary endpoint).^{1,3} In a long-term, open-label safety study, 90% of patients did not require any increase in their dose of PecFent over the four months of treatment and 94% of breakthrough pain episodes did not require additional ‘rescue’ medication within 60 minutes.^{1,4} Patient satisfaction with PecFent was high in the open label study; following 90% of treated episodes patients stated that they were satisfied or very satisfied with PecFent overall.^{1,4,5}

“We welcome the AWMSG’s decision to recommend PecFent within NHS Wales. Often many patients experiencing breakthrough pain in cancer are inadequately treated,” said Eric Low, chief executive of Myeloma UK. “PecFent represents a new, effective treatment approach for patients suffering from the often excruciating and debilitating episodes of breakthrough cancer pain.”

In the clinical trial program, the use of PecFent in the treatment of breakthrough pain in cancer was associated with the occurrence of adverse events typical of opioid medication in this population. The most frequently reported adverse events were vomiting, nausea, and constipation. The majority of such events were mild to moderate in intensity and adverse effects assessed as treatment-related led to study withdrawal in 3.9% of patients.^{2,3,4}

PecFent may cause serious adverse effects such as tolerance or dependence, respiratory depression and bradycardia, and the product must only be used in patients who are already on established maintenance opioid therapy and are therefore tolerant to opioids. Patients must be closely monitored in the titration process. Prescribers should refer to the summary of product characteristics before prescribing.

Breakthrough pain in cancer (BTPc) is an intense, sudden pain that is often unpredictable and debilitating and occurs despite otherwise appropriate opioid therapy for background pain.^{6,7,8} BTPc has a different profile from background pain. BTPc often has high intensity, a rapid onset, usually reaching maximum intensity within five minutes, and a short duration, lasting between 30 and 60 minutes per episode. On average, BTPc affects more than half of patients with cancer and may interfere with patients' health and ability to engage in daily living activities.⁸

About PecFent[®]▼ (fentanyl pectin nasal spray)

PecFent is marketed in Europe where it is presently available in the five countries, including the United Kingdom. PecFent is known as Lazanda[®] (fentanyl) nasal spray in the United States where it was recently approved by the U.S. Food and Drug Administration (FDA).

The European Marketing Authorization of PecFent was based on the review of a comprehensive global clinical data package including three phase 3 studies involving more than 650 patients and more than 100 investigational sites from across four continents and 13 countries, including the United States, United Kingdom, Germany, France, Spain and Italy.

PecFent contains fentanyl a highly potent opioid analgesic and uses Archimedes Pharma's innovative patented drug delivery system, PecSys[®]. PecFent, incorporating PecSys technology, delivers fentanyl in a rapid, but controlled manner and is designed to deliver a fine mist spray to a mucus membrane, in this case the nasal membrane. Each spray of PecFent forms a gel when it contacts the nasal mucosa; fentanyl is then rapidly absorbed across the mucus membrane and directly into the blood stream.

Please also refer to the complete [Summary of Product Characteristics](#) available at www.PecFent.com.

About Archimedes Pharma

Archimedes Pharma is an international specialty pharmaceutical company providing novel and advanced treatments to address unmet needs for people living with serious or life-threatening chronic and debilitating illnesses. Archimedes Pharma markets a diverse portfolio of speciality products and has operations in the U.S. and throughout Europe. Archimedes Pharma UK Limited is a subsidiary of Archimedes Pharma Ltd. For more information, please visit: www.ArchimedesPharma.com.

Lazanda[®], PecFent[®], and PecSys[®] are registered trademarks of Archimedes Development Ltd.

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