

French Medical Societies Recommend Transmucosal Fentanyl As First Line Treatment for Breakthrough Pain in Cancer

PecFent^{®▼} (fentanyl pectin nasal spray) - now available in France – is a novel intranasal delivery that provides clinically meaningful pain relief for breakthrough pain in cancer

Paris, France, 8 November 2011 – Archimedes Pharma France SARL, a subsidiary of Archimedes Pharma Ltd., today announced that an expert medical panel designated by three medical societies - the French Association for Cancer Care Support (AFSOS), French Society for the Study and Treatment of Pain (SFETD) and the French Society for Accompaniment and Palliative Care (SFAP) - has released new recommendations stating that the transmucosal fentanyl medicine class be a first line treatment for breakthrough pain in cancer (BTPc). In addition, the group determined that transmucosal fentanyl is suitable for both predictable and unpredictable breakthrough pain episodes.

“We are pleased with the recommendation by the French expert medical panel headed by Dr. Philippe Poulain, as it confirms the need for better treatment for the management of breakthrough pain in cancer patients,” said André Abric, General Manager, Archimedes Pharma France SARL. *“Patients living with this intense and excruciating pain need a rapid-acting treatment that they can rely on. We see the availability of PecFent^{®▼} in France as a step forward in the care of patients suffering from breakthrough pain in cancer.”*

The expert group recommendation follows the reimbursement agreement of PecFent^{®▼} by the *Haute Autorité de Santé* (HAS) in February 2011. The HAS reviewed clinical data from three phase 3 studies involving more than 500 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, onset of pain relief occurred rapidly (as early as 5 minutes) and was clinically meaningful at 10 minutes after dosing.^{1,2}

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

“As we were evaluating transmucosal Fentanyl for the new treatment breakthrough pain in cancer guidelines, we were pleased to welcome a new, high technology nasal route product such as PecFent^{®▼} for the treatment of breakthrough pain episodes, which are still insufficiently taken care of in France to date” commented Pr Alain Serrie, Hôpital Lariboisière, Paris.

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}

Typical opioid adverse reactions are to be expected with PecFent. Frequently, these will cease or decrease in intensity with continued use of the medicinal product, as the patient is titrated to the most appropriate dose. However, the most serious adverse reactions are respiratory depression (potentially leading to apnoea or respiratory arrest), circulatory depression, hypotension and shock and all patients should be monitored for these.¹

Breakthrough pain in cancer is an intense, sudden pain that is often unpredictable and debilitating and occurs despite otherwise appropriate opioid therapy for background pain.^{5,6,7} 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 on average between 30 to 60 minutes per episode. BTPc affects more than half of patients with cancer and may interfere with patients' health and ability to engage in daily living activities.⁷

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

PecFent[®]▼ is marketed in Europe where it is currently available in six countries, including France. PecFent[®]▼ is known as Lazanda[®] (fentanyl) nasal spray in the United States where it is currently available. Lazanda was approved by the U.S. Food and Drug Administration (FDA) in June 2011.

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 500 patients, over 42,000 BTPc episodes treated 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 avoiding the first bypass liver metabolism.

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

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 specialty products and has operations in the U.S. and throughout Europe. Archimedes Pharma France SARL is a subsidiary of Archimedes Pharma Ltd. For more information, please visit: www.ArchimedesPharma.com.

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