



ARCHIMEDES PHARMA ANNOUNCES PUBLICATION OF A PIVOTAL CLINICAL STUDY OF FENTANYL PECTIN NASAL SPRAY (FPNS) IN PAIN, THE PEER-REVIEWED JOURNAL FROM THE INTERNATIONAL ASSOCIATION FOR THE STUDY OF PAIN

BEDMINSTER, NJ, USA, 4 October 2010: Archimedes Pharma US Inc. today announced publication of results from a pivotal clinical study of Fentanyl Pectin Nasal Spray (FPNS) in the treatment of breakthrough cancer pain (BTCP). The article, entitled 'A multicenter, placebo-controlled, double-blind, multiple-crossover study of Fentanyl Pectin Nasal Spray (FPNS) in the treatment of breakthrough cancer pain,' has been published in Pain, the peer-reviewed journal from the International Association for the Study of Pain.

This randomized, placebo-controlled, double-blind study assessed the efficacy and tolerability of FPNS in cancer patients with breakthrough pain in spite of receiving adequate background opioid therapy. The abstract of the study is available at www.ncbi.nlm.nih.gov/pubmed/20800358.

This study met its primary endpoint in demonstrating a significant difference in summed pain intensity difference 30 minutes after dosing (SPID30; $p < 0.0001$). In addition, significant benefits in pain intensity were noted at five minutes after dosing and were maintained to the end of the assessment period. Adverse events in the study were typical of an opioid medication in this population. The most frequently reported adverse events were vomiting, nausea, disease progression and constipation; the majority of such events were mild to moderate in intensity.

The trial's lead investigator, Dr. Russell Portenoy, chairman of the Department of Pain Medicine at New York's Beth Israel Hospital, said, 'Both the prevalence and negative impact of breakthrough cancer pain support the need for new treatments. A rapid onset formulation has a clear rationale, potentially addressing the well documented mismatch between the time course of most breakthrough pains and the time action relationship of oral drugs.'

Jeff Buchalter, President and CEO of Archimedes Pharma, commented, 'BTCP, which remains under recognized and inadequately managed, affects up to 95% of all cancer patients. FPNS' proprietary pectin-based transmucosal delivery system is characterized by reduced time to onset of effect, which helps overcome one limitation associated with treatment by conventional opioids.'

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Notes to Editors.

About Archimedes Pharma.

Archimedes Pharma is an international specialty pharmaceutical company focused on the oncology, pain, neurology, and critical care sectors. Archimedes Pharma is marketing an expanding portfolio of specialist products to hospital-based prescribers in Europe and has established commercial organizations in the UK, US, France, Germany, Ireland, and Spain.

Archimedes Pharma's portfolio includes an innovative fentanyl nasal spray, PecFent[®], approved in Europe for the treatment of breakthrough cancer pain in adults who are already receiving maintenance opioid therapy for chronic cancer pain, and is under review by the US Food and Drug Administration (FDA).

PecFent[®].

PecFent is an innovative fentanyl citrate nasal spray that has been granted Marketing Authorization by the European Medicines Agency for the treatment of breakthrough cancer pain in adults who are already receiving maintenance opioid therapy for chronic cancer pain.

About Breakthrough Cancer Pain (BTCP).

Breakthrough cancer pain affects up to 95% of all cancer patients with pain and is characterized by sudden, unpredictable episodes of intense pain that occur despite background pain medication. This pain is rapid in onset, usually reaching maximum intensity in five minutes and lasting for 30 to 60 minutes.

For more information, please visit: www.archimedespharma.com

