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CARTA AL DIRECTOR

Archimedes Pharma announces first positive phase III clinical trial results for NasalFent®

Sr. Director:

Archimedes Pharma Limited, the UK based, pan-European specialty pharmaceutical company, today announces positive headline phase III results for NasalFent®, the company's innovative fentanyl citrate nasal spray, developed to provide fast, effective and convenient treatment for breakthrough cancer pain.

Breakthrough cancer pain affects up to 95% of all cancer patients and is characterised by sudden, unpredictable episodes of intense pain that occur despite background pain medication. This pain is rapid in onset, often reaching maximum intensity in 5 min with duration of 30-60 min.

NasalFent® met the primary efficacy endpoint in study 043, a pivotal phase III clinical study for the product. Patients treated with NasalFent® showed a highly statistically significant improvement in Summary of Pain Intensity Difference at 30 min (SPID30) compared to placebo ($p < 0.001$), meaning a greater reduction in pain.

Patients also reported statistically significant differences in pain scores with NasalFent® compared to placebo within 5 min of dosing. NasalFent® is the first product to have demonstrated, in a robust large scale phase III programme, onset of pain relief as early as 5 min. The improvement in pain was maintained for 60 min after dosing with statistically significant results at all measured time points.

NasalFent® showed both consistent effectiveness and high acceptability; 92% of patients completed the double-blind part of the study and 87% of patients elected to continue therapy with NasalFent® in a long term phase III safety study.

Russell K. Portenoy, MD, Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center, New York and Principal Investigator for the NasalFent® study programme, stated: "Breakthrough cancer pain is a significant clinical problem and there is a clear need for new analgesic formulations that are safe and effective, and provide pain relief in a time frame consistent with the rapid time course of most breakthrough pain episodes".

Study 043 was conducted in the Americas, principally the USA, and involved 36 expert investigational sites. A total of 139 patients were screened and 114 (82%) entered the open dose titration phase. Eighty three (83) patients participated in the double-blind, placebo-controlled portion of the study. The protocol for study 043 was agreed with the FDA and is very close in design to studies for approved fentanyl-based products for breakthrough cancer pain.

Richard de Souza, CEO of Archimedes, commented: "We are pleased with the study results which position NasalFent®, the first real intranasal form of fentanyl, as a product that redefines the standard of care for patients suffering with Breakthrough cancer pain. This achievement validates our business model which is to build a fast growing commercial organisation capable of marketing the pipeline of products built around our proprietary nasal technology and developed by our in-house team".

NasalFent® consists of fentanyl in an aqueous solution delivered as a low volume nasal spray. The formulation incorporates PecSys™, Archimedes' proprietary enabling drug delivery technology.

NasalFent® is designed to optimise the absorption of Fentanyl across the nasal mucosa, allowing rapid absorption for fast onset of pain relief but modulating the maximum amount of fentanyl absorbed in order to minimize side effects.

Donald R.Taylor, MD, Director of the Comprehensive Pain Care Centre, Marietta, Georgia added: "NasalFent®, a new analgesic for breakthrough cancer pain, clearly provides more rapid pain relief than traditional breakthrough cancer pain medications and is well accepted by patients. It is also uniquely useful for patients with swallowing difficulties due to their cancer or its treatment".

Archimedes intends to publish full results for 043, along with additional data on the pharmacokinetic and pharmacodynamic profile of NasalFent® compared current therapies, at a series of scientific conferences in 2009.

About NasalFent®

NasalFent® is an innovative fentanyl citrate nasal spray aimed at providing a fast, effective and convenient treatment for breakthrough cancer pain — sudden, unpredictable episodes of intense pain that occur despite background pain medication and which can affect up to 95% of cancer patients with pain.

NasalFent® uses Archimedes proprietary PecSys™ nasal drug delivery system to ensure rapid, but controlled, delivery of fentanyl to match the time-course of the typical breakthrough pain episode experienced by these patients.

An international phase III clinical development programme is approaching completion and the product is targeted for launch in 2010. First results from study 043 show that NasalFent® achieved its primary efficacy objective of a significant improvement in pain versus placebo as assessed by SPID30. In addition NasalFent® showed a significant difference in pain scores within 5 min of dosing, becoming the first product for this indication to show efficacy at this very early time point post-dosing in a large phase III study.

Fentanyl is a highly effective opiate analgesic and is seen as the drug of choice for breakthrough cancer pain.

However, there remains a need for a presentation that provides fast and reliable onset of action coupled with ease of use and high patient acceptability. Archimedes believes NasalFent® offers potential benefits over currently marketed oral and injectable presentations in these key parameters.

Michael Clark

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