



ARCHIMEDES PHARMA RECEIVED EUROPEAN MARKETING AUTHORISATION FOR PECFENT® FOR THE TREATMENT OF BREATHROUGH CANCER PAIN

READING, UK, 1 September 2010: Archimedes Pharma Ltd., a leading international specialty pharma company, today announced that the European Commission has granted marketing authorisation for its lead product, PecFent*, an innovative fentanyl nasal spray for the treatment of breakthrough cancer pain (BTCP) in adults who are already receiving maintenance opioid therapy for chronic cancer pain.

Breakthrough cancer pain is sudden, unpredictable episodes of pain that are severe to excruciating in intensity; it affects 24% to 95% (average 62%) of all cancer patients despite background pain medication.ⁱ Episodes can often reach maximum intensity in five minutes typically lasting 30-60 minutes.ⁱⁱ Most people who have breakthrough cancer pain experience several episodes a day.

PecFent contains fentanyl, a highly potent opioid analgesic and uses an Archimedes Pharma nasal drug delivery system (PecSys™) to deliver fentanyl in a rapid but controlled manner designed to match the time course of the typical breakthrough pain episode. In two randomized, well-controlled, double blind, phase III clinical trials, PecFent demonstrated onset of pain relief as early as five minutes as well as clinically meaningful pain relief within 10 minutes.^{iii, iv, v}

Jeffrey H. Buchalter, President and Chief Executive Officer of Archimedes Pharma, commented: "The grant of European marketing authorisation for PecFent provides a new therapy to improve the treatment options for adult patients with breakthrough cancer pain. This is also a transformative milestone for Archimedes Pharma as we have established commercial operations in Europe and look forward to launching PecFent in major European markets in the coming months."

Prof. Marie Fallon, St Columba's Hospice Chair of Palliative Medicine, University of Edinburgh, Edinburgh Cancer Research Centre (CRUK) Western General Hospital, Edinburgh, UK, commented: "The availability of this significant innovation is very important. Being a nasal spray, its ease of use allows patients to treat their breakthrough cancer pain episodes conveniently, wherever they are, and its unique delivery system provides fast onset of pain relief meaning so they can manage these episodes effectively. This is absolutely crucial for cancer patients and PecFent offers real hope for an improvement in their quality of life."

The marketing authorisation is based on the largest ever clinical development programme in breakthrough cancer pain, which involved three Phase III studies including an active comparator study and a large long-term safety and acceptability study.^{vi} The programme included more than 650 patients and more than 100 investigational sites from the US, UK, Germany, France, Spain and Italy, and in total 13 countries across four continents.

Archimedes Pharma submitted a New Drug Application (NDA) for the product to the US Food and Drug Administration (FDA) in August 2009 and is in the process of establishing a US commercial organisation to market the drug in the US once approved.

**PecFent was previously known as NasalFent.*

For further information please contact:

Citigate Dewe Rogerson (UK and Europe): Chris Gardner/Amber Bielecka, +44 207 638 9571, amberbielecka@citigatedr.co.uk

Tiberend Strategic Advisors, Inc. (USA): Gregory Tiberend/Tamara Bright, +1 212-827-0020, gtiberend@tiberendstrategicadvisors.com / tbright@tiberendstrategicadvisors.com

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 the US and has established commercial organizations in the UK, US, France, Germany, Ireland, and Spain.

Products currently marketed in Europe by Archimedes Pharma include: Gliadel, a biodegradable wafer impregnated with carmustine for high-grade glioma; Zomorph, an oral sustained release morphine product for moderate to severe pain, particularly cancer pain; Oramorph, a liquid immediate release morphine product also indicated for moderate to severe pain; Apomorphine Injection for motor fluctuations in advanced Parkinson's disease; and Pabrinex, a high potency vitamin formulation used to treat the symptoms of malnutrition especially in patients with alcohol misuse problems.

Archimedes Pharma is also developing a robust, high-value pipeline of in-house pain therapeutics, Parkinson's disease and critical care. It applies its world-class drug delivery technologies to proven molecules that have yet to achieve their market potential due to their current mode of delivery. This approach reduces the company's development risk, while delivering significant clinical and commercial benefits.

PecFent®.

Archimedes Pharma's company-transforming product PecFent®, an innovative fentanyl citrate nasal spray, is now licensed in the European Union for the treatment of breakthrough cancer pain in adults who are already receiving maintenance opioid therapy for chronic cancer pain.

PecFent® is an aqueous fentanyl citrate solution utilizing Archimedes Pharma's proprietary PecSys™ technology. The PecFent® solution has a low viscosity and is easily delivered in a low volume of 100ml using a nasal spray pump. The pump produces a fine mist of similarly sized spray droplets that are deposited into the front of the nostril. The calcium ions present on the nasal mucosa cause the pectin to form a thin gel layer, which allows fentanyl to be retained on the nasal mucosa, allowing a rapid but controlled absorption into the systemic circulation. The PecSys™ technology avoids problems associated with simple solutions used in nasal sprays, such as dripping or swallowing of the drug solution.

In the clinical trial program, the use of PecFent in the treatment of breakthrough cancer pain was associated with the occurrence of adverse events typical of opioid medication in this population. The most frequently reported were vomiting, nausea, disease progression 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.

Archimedes Pharma's technologies - ChiSys®, PecSys™ and TARGIT® - are also used in a number of partnered products in late-stage clinical development. ChiSys®, an innovative drug delivery technology that enhances the residence time of molecules on mucosal membranes, has proven potential for vaccine delivery. Pre-clinical and clinical studies of nasally administered vaccines have demonstrated enhanced immune response. PecSys™ is Archimedes Pharma's patented drug delivery system built around its novel pectin technology, designed to maximize the potential of systemically absorbed drugs by enhancing drug performance and improving patient acceptance.

Please also refer to the complete Summary of Product Characteristics available at www.pecfent.com.

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.

About Warburg Pincus.

Warburg Pincus is a leading global private equity firm. The firm has more than \$30 billion in assets under management. Its active portfolio of more than 100 companies is highly diversified by stage, sector and geography. Warburg Pincus is a growth investor and an experienced partner to management teams seeking to build durable companies with sustainable value. Founded in 1966, Warburg Pincus has raised 12 private equity funds which have invested more than \$35 billion in approximately 600 companies in more than 30 countries. Since the firm's first European transaction in 1983, Warburg Pincus has invested more than \$6 billion in European companies, including investments in Archimedes, Eurand and ProStrakan. Additional life science investments include Allos Therapeutics, Ganic Pharmaceuticals, InterMune, Rib-X Pharmaceuticals and ZymoGenetics. The firm has offices in Beijing, Frankfurt, Hong Kong, London, Mumbai, New York, San Francisco, Shanghai and Tokyo. For more information, please visit www.warburgpincus.com.

About Novo A/S and Novo Growth Equity.

Novo A/S is the holding and investment company of the Novo Group, and is wholly owned by the Novo Nordisk Foundation. Novo A/S was formed in 1999 to actively manage the assets of the foundation. It employs about 30 people and has approximately USD 15 billion of assets under management. These includes significant shareholdings in the publicly listed Novo Nordisk A/S (NYSE: NVO) and Novozymes A/S (NVZMF.PK), Novo A/S provides seed, venture and growth capital to development stage companies within life science and biotechnology, as well

as manages a broad portfolio of financial assets. Novo A/S is committing up to USD 300 million annually to its investments in seed, venture and growth equity life science companies. Of this, nearly two-thirds are directed to the Novo Growth Equity activities focusing on investment in promising late stage companies with near term commercial potential. For further information please visit www.novo.dk.

Notes.

ⁱ Svendsen KB, Andersen S, Arnason S, et al. Breakthrough pain in malignant and non-malignant diseases: a review of prevalence, characteristics and mechanisms. *Eur J Pain*. 2005;9:195-206. ⁱⁱ Portenoy RK, Hagen NA. Breakthrough pain: definition, prevalence and characteristics. *Pain*. 1990;41:273-281. ⁱⁱⁱ Portenoy, R. Burton, A. Wallace, M. et al. The Efficacy, Onset of Action and Tolerability of Fentanyl Pectin Nasal Spray (FPNS) With PecSys[®] in the Treatment of Breakthrough Cancer Pain (BTCP): A Multicentre, Placebo- Controlled, Double-Blind Crossover Study. Poster presented at the 11th Congress of the European Association for Palliative Care (EAPC); 7–10 May 2009; Vienna, Austria. ^{iv} Burton, A. Wallace, M. Taylor, D. et al. Fentanyl Pectin Nasal Spray (FPNS) With PecSys[®]: Onset of Action, Consistency, and Acceptability in Breakthrough Cancer Pain (BTCP). Poster Presented at the Annual Meeting of the American Pain Society, 7–9 May 2009; San Diego, CA. ^v Fallon, M. Gatti, A. Davies, A. et al. Efficacy, Safety and Patient Acceptability of Fentanyl Pectin Nasal spray Compared with Immediate- Release Morphine Sulphate Tablets in the Treatment of Breakthrough Cancer Pain: A Multicentre, Double-Blind, Double-Dummy, Multiple-Crossover Study. Poster Presented at the joint 15th Congress of the European Cancer Organisation and 34th Congress of the European Society for Medical Oncology; 20–24 September 2009; Berlin, Germany. ^v Torres, L. Radbruch, L. Reale, C. et al. Long-term Safety, Tolerability and Consistency of Effect of Fentanyl Pectin Nasal Spray in Opioid-Tolerant Patients in the Treatment of Breakthrough Cancer Pain. Poster Presented at the joint 15th Congress of the European Cancer Organisation and 34th Congress of the European Society for Medical Oncology; 20–24 September 2009; Berlin, Germany

