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Nautilus Neurosciences and APR Applied Pharma Research s.a. Announce Extension of Patent Protection for CAMBIA[™] (diclofenac potassium for oral solution) through 2026

BEDMINSTER, N.J., & BALERNA, SWITZERLAND September 8th, 2010 — Nautilus Neurosciences, Inc. ("Nautilus"), a neurology-focused specialty pharmaceutical company headquartered in New Jersey, and APR Applied Pharma Research s.a. ("APR"), a leading drug developer and delivery technology provider based in Switzerland, announced today that CAMBIA[™] (diclofenac potassium for oral solution) is now protected by an additional Orange Book listed patent through June 16, 2026. CAMBIA[™] is approved in the United States for the acute treatment of migraine with or without aura and was launched in the United States in June 2010.

"The extension of our patent protection for CAMBIA[™] through 2026 allows Nautilus to continue to expand our efforts to make CAMBIA[™] available to the millions of Americans who suffer from migraines," said James Fares, chairman and CEO, Nautilus Neurosciences. "It is rare to have up to 16 years to build the value and scope of a franchise and we expect CAMBIA[™] to serve as a cornerstone of our Neurology focused product line for many years."

CAMBIA[™], a novel, water-soluble, buffered diclofenac potassium powder, is the only prescription nonsteroidal anti-inflammatory drug (NSAID) available for the acute treatment of migraine. Engineered using APR's Dynamic Buffering Technology[™] (DBT), a patented absorption-enhancing technology, CAMBIA[™] is specifically designed for fast, effective relief from the symptoms of migraine. CAMBIA[™] enters the bloodstream quickly and readily achieves peak plasma concentrations, providing rapid onset of pain relief via oral therapy without increasing the patient's total exposure to diclofenac.

"The issuance and listing of this new patent that includes claims for both the drug substance and the acute treatment of migraine with or without aura reflects the compelling benefit our technology provides to CAMBIA™," said Paolo Galfetti, CEO of APR.

Migraine affects more than 36 million people in the United States, 75 percent of whom are women. According to a survey published in the *Journal of the American Board of Family Medicine*, many migraineurs hope to find a better treatment for their migraines, with less than one fifth of patients describing themselves as "very satisfied" with their current treatment, and more than one quarter describing themselves as being "dissatisfied" with treatment.

About Nautilus Neurosciences, Inc.

Nautilus Neurosciences is a neurology-focused specialty pharmaceutical company committed to providing the health care community with medically relevant products and services that directly benefit those affected by neurologic disorders. Nautilus is backed by Tailwind Capital and Galen Partners. For more information, please visit <u>www.nautilusneurosciences.com</u>.





About APR Applied Pharma Research S.A.

APR Applied Pharma Research s.a. is an independent, international and integrated Healthcare Company headquartered in Switzerland with a subsidiary in Charlotte (NC, USA) and focused on three major areas: Delivering, Funding and Supporting Innovation in Healthcare. In particular, APR develops and licenses innovative, value added and patented healthcare products and proprietary drug delivery systems primarily in the oral and topical fields; APR also invests in companies or early stage innovative projects and provides a balanced mix of equity funding and/or financing together with APR's development, scientific, technical, marketing, licensing and management skills and know how; finally, APR supports biotech and pharmaceutical companies in the development of new pharmaceutical projects by providing on a contract basis added value, consultancy and R&D services under contract using a General Contractor approach. APR has entered into licensing and partnership agreements with pharmaceutical companies in over 100 countries worldwide with international sales on a worldwide basis. For more information about APR, please visit www.apr.ch.

Nautilus Contact:

James Fares, Chairman and CEO Nautilus Neurosciences, Inc. 908-393-7801 jfares@nautilusneurosciences.com

APR Contacts:

Paolo Galfetti, CEO APR Applied Pharma Research 41-91-695-7020 Paolo.Galfetti@apr.ch

Aldo Donati, Vice President Applied Pharma Research USA +1 (704) 365-3232 aldo.donati@apr.ch

Indication

CAMBIA is a non-steroidal anti-inflammatory drug (NSAID) indicated for the acute treatment of migraine attacks with or without aura in adults 18 years of age or older. CAMBIA is not indicated for prophylactic therapy or for cluster headache.

Important Safety Information

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS NSAIDs, including CAMBIA, may increase the risk of serious cardiovascular (CV) thrombotic events, myocardial infarction, and stroke, which can be fatal. Risk may increase with duration of use or in patients with CV disease or risk factors for CV disease. CAMBIA is contraindicated for peri-operative pain in coronary artery bypass graft surgery. NSAIDs increase the risk of gastrointestinal (GI) adverse events, including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk.





Use the lowest effective dose for the shortest possible duration. Long-term administration of NSAIDs can result in serious and potentially fatal events, including CV thrombotic events or GI reactions.

CAMBIA is contraindicated in patients with hypersensitivity to diclofenac or other NSAIDs, and in patients with preexisting asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic-like reactions have been reported in such patients. Anaphylactic reactions may also occur in patients with the aspirin triad or in patients without prior exposure to CAMBIA. CAMBIA is contraindicated in patients with the aspirin triad. Discontinue immediately if an anaphylactic reaction occurs.

Renal papillary necrosis and other renal injury may occur with long-term use of NSAIDs. Use CAMBIA with caution in patients at risk, including the elderly, those taking diuretics or ACE inhibitors, those with renal impairment, heart failure, or liver impairment. CAMBIA is not recommended in patients with advanced renal disease.

Use caution when prescribing CAMBIA with drugs known to be hepatotoxic (eg, acetaminophen, certain antibiotics, antiepileptics). Warn patients to avoid acetaminophen containing products while taking CAMBIA. The liver metabolizes almost 100% of diclofenac, and there is insufficient information to support dosing recommendations in patients with hepatic insufficiency. Hepatic effects range from transaminase elevations to liver failure. Discontinue CAMBIA immediately if abnormal liver tests persist or worsen.

NSAIDs can lead to new onset or worsening of preexisting hypertension. Monitor blood pressure closely during therapy. Patients taking ACE inhibitors, thiazides, or loop diuretics may have impaired response to these therapies when taking NSAIDs. Note that fluid retention and edema have been observed in some patients taking NSAIDs. Use CAMBIA with caution in patients with fluid retention or heart failure.

Using CAMBIA with other NSAIDs (eg, aspirin) or with anticoagulants (eg, warfarin) is not advised due to increased risk of serious adverse events, such as GI bleeding. Use with caution in patients with a history of ulcers or GI bleeding. Anemia may occur in patients on NSAIDs. In patients on long-term therapy, check hemoglobin or hematocrit upon any sign or symptom of anemia or blood loss.

NSAIDs, including CAMBIA, can cause serious skin reactions including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, which can be fatal. Discontinue use immediately if rash or other signs of local skin reaction occur.

CAMBIA can harm fetuses. Starting at 30 weeks' gestation, pregnant women should avoid CAMBIA and other NSAIDs as premature closure of the ductus arteriosus in the fetus may occur. Use with caution in nursing mothers as it is not known if diclofenac is excreted in human milk.

The most common adverse events in clinical trials with CAMBIA were nausea and dizziness.