FDA GRANTS ORPHAN-DRUG DESIGNATION TO AN ORAL LIQUID SUSPENSION OF CELECOXIB TO TREAT ARTHRITIS IN CHILDREN

FDA grants orphan-drug designation for NuBioPharma,LLC's Nu-Celecoxib™ (celecoxib) an oral liquid suspension to treat pediatric juvenile idiopathic arthritis.

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NuBioPharma, LLC announces that Nu-Celecoxib™ (celecoxib) oral liquid suspension is granted orphan-drug designation by the fda for the treatment of pediatric juvenile idiopathic arthritis

NuBioPharma,LLC is the developer and formulator of Nu-Celecoxib™ (celecoxib) announced today that Nu-Celecoxib™ (celecoxib) Oral Liquid Suspension was been granted Orphan-Drug designation by the FDA for the treatment of pediatric Juvenile Idiopathic Arthritis (JIA). However, unlike the current treatments for JIA where parents must often empty the contents of Celebrex® capsule and sprinkle on applesauce to give to children, Nu-Celecoxib™ oral liquid suspension with child-friendly flavors will enable measurement of precise doses that can easily be administered.

JIA is the most common type of arthritis in children under the age of 17. JIA causes persistent joint pain, swelling and stiffness. Children may also become quite ill, presenting with flu-like symptoms and rash that persist. Late effects of arthritis include stiff, bent joints due to fibrosis and joint damage. It can also cause inflammation of eyes called Uveitis, if untreated can lead to blindness. Some children may experience symptoms for only a few months, while other have symptoms for the rest of their lives. According to a recent study (Journal of Rheumatology 2013 Jul;40(7):1218-25) prevalence of JIA among children in a managed care population is 44.7 per 100,000 which results in an estimate of 141,300 patients in the United States with JIA.

In 2006, the FDA approved dosing with 50 mg and 100 mg Celebrex® capsules to treat the signs and symptoms of JIA in children aged 2–17 years. It was recommended that children who have difficulty in swallowing capsules should empty the contents of a capsule and sprinkle on applesauce for dosing. Celecoxib has been a very useful treatment option for pain relief for children with JIA. However, an oral, pediatric appropriate celecoxib formulation for these children has been lacking. “Using current capsule dosing for younger children results in higher doses,” remarked Ajay Ajmani MD, Chief Medical Officer at NuBioPharma. “Nu-Celecoxib™ should offer quality, accuracy and safety, potentially benefiting a wide range of children and the healthcare professionals who treat them.”

The FDA provides Orphan Drug Designation status to drugs intended to treat rare diseases that affect fewer than 200,000 people in the US. The designation provides 7-year marketing exclusivity period, and has certain incentives, including federal grants, tax credits and a waiver of Prescription Drug User Fee Act filing fees.

Forward-Looking Statement: This release includes “forward statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of NuBioPharma and are subject to significant risks and uncertainties. There are no guarantees with respect to pipeline products that, they will receive necessary regulatory approvals or that they will prove commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, industry conditions, competition; general economic factors, interest rates, currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; NuBioPharma’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of NuBioPharma’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and regulatory actions.

NuBioPharma’s undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise

About NuBioPharma, LLC (www.nubiopharma.com)
NuBioPharma, LLC a privately-held pharmaceutical company, founded in 2015 is dedicated to development of novel liquid medications with child-friendly flavors that will improve the quality of lives in pediatric patients.

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