

**Noden Pharma Announces FDA Approval of Tekturna®(aliskiren) Oral Pellets for the Treatment of Hypertension in Adults and Children 6 Years of Age and Older**

DUBLIN, IRELAND, November 14, 2017 – Noden Pharma DAC, a global specialty pharmaceutical company that is focused on acquiring prescription medicines across a broad range of therapeutic areas, announced today the approval by the U.S. Food and Drug Administration of Tekturna®(aliskiren) Oral Pellets for the treatment of hypertension in adults and children six years of age and older. The new formulation and pediatric indication were approved through the FDA priority review process. Noden Pharma DAC is a wholly-owned subsidiary of PDL BioPharma, Inc.

“This expanded indication for Tekturna provides an additional option for pediatric hypertensive patients,” said Alan Markey, acting CEO of Noden Pharma DAC. “In addition, it provides an alternative dosing option for adults with hypertension.”

According to hypertension guidelines published by the American Academy of Pediatrics (AAP) the prevalence of clinical hypertension in children and adolescents is ~3.5%. The prevalence of persistently elevated blood pressure is ~2.2% to 3.5%, with higher rates among children and adolescents who are overweight and those with obesity.<sup>1</sup>

The efficacy and safety of Tekturna® for pediatric use was evaluated in an 8-week randomized, double-blind trial in 267 hypertensive patients 6 to 17 years of age, including 208 patients treated for 52 weeks, following the 8-week study. During the initial dose-response phase, Tekturna® reduced both systolic and diastolic blood pressure in a weight-based dose-dependent manner. These studies did not reveal any unanticipated adverse reactions. Adverse reactions in pediatric patients six years of age and older are expected to be similar to those seen in adults.

Tekturna® Oral Pellets may be taken by carefully opening the dispensing capsule and emptying the contents into a spoon then into the mouth, and then swallowing right away with water or milk (dairy or soy-based) without chewing or crushing. Alternatively, the contents can be taken orally immediately after mixing with specified dosing vehicles.

John McLaughlin, CEO of PDL BioPharma, said, “Our investment in Noden has provided us with a platform upon which to build a specialty pharmaceutical company, and we are pleased to see the team at Noden execute this important expansion of the label for Tekturna®.”

Noden plans to make Tekturna® Oral Pellets available in 2018.

**For full prescribing information and patient information for TEKTURNA, including BOXED Warning, Contraindications, and Warnings and Precautions, please visit [www.tekturna.com](http://www.tekturna.com).**

**INDICATIONS and USAGE**

TEKTURNA is indicated for the treatment of hypertension in adults and children 6 years of age and older, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from a wide variety of pharmacologic classes. There are no controlled trials

demonstrating risk reduction with TEKTRNA. Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake. Many patients will require more than one drug to achieve blood pressure goals.

#### IMPORTANT SAFETY INFORMATION

##### **WARNING: FETAL TOXICITY**

- **When pregnancy is detected, discontinue TEKTRNA as soon as possible. (5.1)**
- **Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus. (5.1)**

**Contraindications:** Do not use TEKTRNA with angiotensin receptor blockers (ARBs) or angiotensin-converting enzyme inhibitors (ACEIs) in patients with diabetes because of increased risk of renal impairment, hyperkalemia, and hypotension. TEKTRNA is contraindicated in patients with hypersensitivity to any of its components. Tekturna is contraindicated in pediatric patients less than 2 years of age.

**Anaphylactic Reactions and Head and Neck Angioedema:** Hypersensitivity reactions such as anaphylactic reactions and angioedema of the face, extremities, lips, tongue, glottis, and/or larynx have been reported in patients treated with aliskiren and have necessitated hospitalization and intubation. This may occur at any time during treatment and has occurred in patients with and without a history of angioedema with ACEIs or angiotensin receptor antagonists. Discontinue TEKTRNA immediately in patients who develop anaphylactic reactions or angioedema, and do not readminister.

**Hypotension:** In patients with an activated renin-angiotensin-aldosterone system (RAAS), such as volume- and/or salt-depleted patients receiving high doses of diuretics, symptomatic hypotension may occur in patients receiving RAAS blockers. Correct these conditions before administering TEKTRNA, or start the treatment under close medical supervision.

**Impaired Renal Function:** Avoid combined use of aliskiren with ARBs or ACEIs in patients with renal impairment (creatinine clearance less than 60 mL/min). Monitor renal function periodically in patients receiving aliskiren, as changes in renal function, including acute renal failure, can be caused by drugs that affect the RAAS and by diuretics. Patients whose renal function may depend in part on the activity of the RAAS (e.g. patients with renal artery stenosis, severe heart failure, post-MI, or volume depletion) or patients receiving ARBs, ACEIs, or nonsteroidal anti-inflammatory drugs (NSAIDs), including selective Cyclooxygenase-2 inhibitors (COX-2 inhibitors), may be at particular risk for developing acute renal failure on aliskiren. Consider withholding or discontinuing therapy in patients who develop a clinically significant decrease in renal function. Safety and effectiveness of aliskiren in patients with severe renal impairment (creatinine clearance less than 30 mL/min) has not been established.

**Hyperkalemia:** Monitor serum potassium periodically in patients receiving aliskiren. Drugs that affect the RAAS can cause hyperkalemia. Risk factors for the development of hyperkalemia include renal insufficiency, diabetes, and combination use of aliskiren with ARBs or ACEIs, NSAIDs, potassium supplements, or potassium-sparing diuretics.

**Cyclosporine, or Itraconazole:** Avoid use of TEKTURNA with cyclosporine or itraconazole.

**Common AEs:** Adverse events (AEs) with increased rates for TEKTURNA compared with placebo included diarrhea (2.3% vs 1.2%), cough (1.1% vs 0.6%), rash (1.0% vs 0.3%), hyperkalemia (0.9% vs 0.6%), elevated uric acid (0.4% vs 0.1%), gout (0.2% vs 0.1%), and renal stones (0.2% vs 0%).

**Lactation:** Breastfeeding is not recommended during treatment with TEKTURNA.

**Relationship to meals:** Advise patients to establish a routine pattern for taking TEKTURNA tablets. High-fat meals decrease absorption substantially.

**Overdosage:** Limited data are available and the most likely manifestation of overdosage would be hypotension. If symptomatic hypotension occurs, supportive treatment should be initiated. As aliskiren is poorly dialyzed, hemodialysis is not adequate to treat overexposure.

#### **About Noden Pharma**

Noden Pharma DAC is a global specialty pharmaceutical company that is focused on acquiring prescription medicines across a broad range of therapeutic areas in international markets. The company focuses its resources on acquiring and optimizing established medicines. Corporate headquarters are located in Dublin, Ireland. For more information on Noden Pharma DAC please visit [www.nodenpharma.com](http://www.nodenpharma.com).

Noden Pharma DAC is a wholly-owned subsidiary of PDL BioPharma, Inc. (NASDAQ: PDLI). For more information on PDL BioPharma please visit [www.pdl.com](http://www.pdl.com).

1. Flynn JT, Kaelber DC, Baker-Smith CM, et al. Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents. *Pediatrics*. 2017;140(3):e20171904