

## PRESS RELEASE

### **Results from Pivotal, Phase 3 Trial for SECUADO® (asenapine) Published in *Journal of Clinical Psychiatry***

#### ***First and Only FDA Approved Transdermal System Now Available to Nearly 220 Million Insured Adults Living with Schizophrenia in the U.S.***

**Miami, FL and Jersey City, NJ – December 15, 2020** -- Noven Pharmaceuticals, Inc., a wholly-owned subsidiary of Hisamitsu Pharmaceutical Co., Inc., today announced publication of the results from a pivotal, phase 3 trial, which showed that SECUADO® (asenapine) transdermal system demonstrated significant improvement in Positive and Negative Syndrome Scale (PANSS) total score at Week 6 versus placebo in adult patients with schizophrenia. SECUADO is the first-and-only transdermal patch formulation for the treatment of adults with schizophrenia approved by the U.S. Food and Drug Administration.<sup>1</sup> The data are published in the January/February 2021 edition of the *Journal of Clinical Psychiatry*.<sup>2</sup>

“Asenapine is a well-established treatment option and delivering it transdermally with SECUADO provides a non-intrusive approach and visual confirmation of adherence,” said Leslie Citrome, M.D., M.P.H., Clinical Professor of Psychiatry and Behavioral Sciences, New York Medical College.

“Noven is pleased to offer a transdermal treatment option and is committed to assisting patients and caregivers with resources, including access to support specialists, through our Noven Care Access Network,” said Joel Lippman, M.D., Chief Operating Officer and Chief Medical Officer, Noven Pharmaceuticals, Inc.

The phase 3, multicenter, placebo-controlled, randomized, double-blind, inpatient study included participants 18 years of age or older experiencing an acute exacerbation of schizophrenia. Study participants were randomized (1:1:1) to either SECUADO 7.6 mg/24h or 3.8 mg/24h or placebo.

SECUADO achieved the primary endpoint, demonstrating statistically significant improvement in Positive and Negative Syndrome Scale (PANSS) total score change from baseline to Week 6 compared to placebo. After six weeks of treatment, the difference in the least squares mean (LSM) (SE) change from baseline in PANSS total score was -4.8 (1.634) and -6.6 (1.630) for the SECUADO 7.6 mg/24h and 3.8 mg/24h groups, compared with placebo.

The most commonly observed adverse reactions in ≥5% of patients and twice the rate observed in the placebo group were extrapyramidal disorder, application site reaction, and weight gain.<sup>1</sup> Incidence of application site related treatment-emergent adverse events

was higher for SECUADO (14.2%, 7.6 mg/24h; 15.2%, 3.8 mg/24h) versus placebo (4.4%).

Please click [here](#) for full Prescribing Information, including Boxed Warning.

### **What is SECUADO?**

SECUADO is a prescription medicine used to treat adults with schizophrenia. SECUADO is a transdermal system (patch) you apply to your skin. It is not known if SECUADO is safe and effective in children less than 18 years of age with schizophrenia.

### **IMPORTANT SAFETY INFORMATION**

**SECUADO may cause serious side effects, including:**

- **Increased risk of death in elderly people with dementia-related psychosis. Medicines like SECUADO can raise the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). SECUADO is not approved for the treatment of people with dementia-related psychosis.**
- **Stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that can lead to death.**
- **Neuroleptic Malignant Syndrome (NMS): a serious condition that can lead to death. Immediately remove the patch.** Call your healthcare provider or go to the nearest hospital emergency room right away if you have some or all of the following: high fever, confusion, stiff muscles, increased sweating and changes in your breathing, heart rate and blood pressure.
- **Uncontrolled body movements (tardive dyskinesia).** SECUADO may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away, even if you stop taking SECUADO. Tardive dyskinesia may also start after you stop taking SECUADO.
- **Problems with your metabolism such as:**
  - **High blood sugar (hyperglycemia) and diabetes.** Increases in blood sugar can happen in some people who take SECUADO.  
**Call your healthcare provider if you have any of these symptoms of high blood sugar during treatment with SECUADO:**
    - Feel very thirsty or very hungry
    - Feel sick to your stomach
    - Feel weak or tired
    - Need to urinate more than usual
    - Feel confused, or your breath smells fruity
  - **Increased fat levels (cholesterol and triglycerides) in your blood**
  - **Weight gain.** You and your healthcare provider should check your weight regularly during treatment with SECUADO.
- **Allergic reactions.** You may observe rash, decreased blood pressure or a fast heart rate.
- **Decreased blood pressure (orthostatic hypotension).** You may feel lightheaded or faint when you rise too quickly from a sitting or lying position.

- **Falls.** SECUADO may make you sleepy or dizzy, may cause a decrease in your blood pressure when changing position, and can slow your thinking which may lead to falls.
- **Low white blood cell count.** Your healthcare provider may do blood tests during the first few months of treatment with SECUADO.
- **Irregular heartbeat** or a heartbeat that does not feel normal (QT prolongation)
- **Increased prolactin levels in your blood (hyperprolactinemia).** Your healthcare provider may do blood tests to check your prolactin levels during treatment with SECUADO.
- **Seizures (convulsions)**
- **Impaired thinking and motor skills.** Use caution when operating heavy machinery when using SECUADO.
- **Problems controlling your body temperature so that you feel too warm**
- **Difficulty swallowing**
- **External heat.** Avoid exposing SECUADO to direct external heat sources such as hair dryers, heating pads, electric blankets, heated water beds, etc.
- **Application site reactions. Increased skin irritation may occur if SECUADO is applied for a longer period than instructed or if the same application site is used repeatedly. Use a different application site each day to decrease skin reactions.** If skin reactions continue or spread beyond the application site, tell your healthcare provider. Symptoms of application site reactions may include:
  - Redness
  - Itching
  - Irritation
  - Pimple-like raised skin
  - Pain of the skin
  - Swelling

**Do not use SECUADO if you:**

- Are allergic to asenapine or any other ingredients in SECUADO
- Have severe liver impairment

**Before you use SECUADO, tell your healthcare provider about all of your medical conditions, including if you have or have had:**

- Heart problems or stroke
- Low or high blood pressure
- Diabetes or high blood sugar, or have a family history of diabetes or high blood sugar
- High levels of total cholesterol or triglycerides
- High prolactin levels
- Low white blood cell count
- Seizures
- Liver problems

**Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with SECUADO. It is not known if SECUADO will harm your unborn baby.**

- If you become pregnant during treatment with SECUADO, talk to your healthcare provider about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or go to <https://womensmentalhealth.org/research/pregnancyregistry/>.

Talk to your healthcare provider about the best way to feed your baby during treatment with SECUADO. It is not known if SECUADO passes into your breast milk.

**Tell your healthcare provider about all of the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SECUADO and other medicines may affect each other causing possible serious side effects. SECUADO may affect the way other medicines work, and other medicines may affect how SECUADO works.

**The most common side effects of SECUADO include:**

- Restlessness, difficulty moving, muscle stiffness, tremor
- Skin irritation where the patch is placed
- Weight gain

Tell your healthcare provider if you have any side effects that bothers you or does not go away. These are not all the possible side effects of SECUADO.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <http://www.fda.gov/medwatch> or call 1-800-FDA-1088.

### **About Schizophrenia**

Schizophrenia is a severe, chronic psychiatric disease with a heterogeneous course and symptom profile. The symptoms associated with schizophrenia are disabling and lifelong, and greatly affect a patient's quality of life and social functioning. Symptoms usually start between ages 16 and 30 and fall into three categories: positive, negative and cognitive. Positive symptoms are psychotic behaviors not generally seen in healthy people and can include hallucinations, delusions, thought disorders and movement disorders. Negative symptoms are associated with disruptions to normal emotions and behaviors and can include flat affect (reduced expression of emotions), reduced feelings of pleasure in everyday life, difficulty beginning and sustaining activities and reduced speaking. Cognitive symptoms can include poor executive functioning (the ability to understand information and use it to make decisions), trouble focusing or paying attention and problems with working memory (the ability to use information immediately after learning it).<sup>3</sup>

### **About the Noven Care Access Network**

The Noven Care Access Network (Noven C.A.N.<sup>™</sup>) is designed to provide people living with schizophrenia and their caregivers SECUADO information and resources, including access to a support specialist. Additional information can be found at [SECUADO.com](http://SECUADO.com).

## About Noven

Noven Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of prescription pharmaceutical products. Noven's mission is to develop and offer pharmaceutical products that meaningfully benefit patients around the world, with a commitment to advancing patient care through transdermal drug delivery. Noven is a stand-alone operating subsidiary of Japan-based Hisamitsu Pharmaceutical Co., Inc., serving as Hisamitsu's U.S. platform in prescription pharmaceuticals, and helping Hisamitsu bring the benefits of patch therapy to the world. For more information about Noven, visit [www.noven.com](http://www.noven.com). For information about Hisamitsu, visit [www.hisamitsu.co.jp/english](http://www.hisamitsu.co.jp/english).

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<sup>1</sup> SECUADO [prescribing information]. Miami, FL: Noven Therapeutics LLC; 2019.

<sup>2</sup> Journal of Clinical Psychiatry. Efficacy and Safety of HP-3070, an Asenapine Transdermal System, in Patients With Schizophrenia. [Internet] Available from: <https://www.psychiatrist.com/JCP/article/Pages/asenapine-transdermal-system-for-schizophrenia.aspx>

<sup>3</sup> National Institute of Mental Health. Schizophrenia. [Internet]. Available from: <https://www.nimh.nih.gov/health/statistics/schizophrenia.shtml> Accessed September 2019.

<sup>4</sup> SECUADO® is a registered trademark of Hisamitsu Pharmaceutical Co., Inc.