

PRESS RELEASE

U.S. FDA Approves SECUADO® (asenapine) Transdermal System, the First-and-Only Transdermal Patch for the Treatment of Adults with Schizophrenia

Miami, FL and Jersey City, NJ -- October 15, 2019 -- Noven Pharmaceuticals, Inc., a wholly-owned subsidiary of Hisamitsu Pharmaceutical Co., Inc., today announced the U.S. Food and Drug Administration (FDA) has approved SECUADO® (asenapine) transdermal system, the first-and-only transdermal patch formulation for the treatment of adults with schizophrenia.¹

“As people living with schizophrenia cycle through treatments their therapeutic options narrow, leaving them and their caregivers looking for new treatment options,” said Leslie Citrome, M.D., M.P.H., Clinical Professor of Psychiatry and Behavioral Sciences, New York Medical College. “In addition to offering a new delivery option, transdermal patches can also provide caretakers and healthcare providers with a non-intrusive, visual confirmation that a treatment is being utilized.”

The once-daily transdermal drug delivery system (TDDS) provides sustained concentrations during wear time (24 hours)² of the atypical antipsychotic drug asenapine, a well-established treatment for schizophrenia. A transdermal patch may help to mitigate some of the challenges patients face with the management of their schizophrenia.²

“There is an enormous unmet need for new types of schizophrenia treatments, and Noven is committed to giving people living with this devastating disease and their family members new options that may help them effectively manage their symptoms,” said Dr. Naruhito Higo, Chairman and Chief Executive Officer, Noven Pharmaceuticals, Inc. “We commend the FDA on the approval of SECUADO and look forward to bringing it to market in the U.S. as soon as possible so people living with schizophrenia have a transdermal delivery option for asenapine treatment.”

In the international, Phase 3, double-blind, placebo-controlled study, SECUADO achieved the primary endpoint of statistically significant improvement from baseline in the change of the total Positive and Negative Syndrome Scale (PANSS) compared to placebo at week six. Efficacy and safety were assessed during the six-week treatment period in 616 adults living with schizophrenia. Additionally, SECUADO demonstrated statistically significant improvement in Clinical Global Impression-Severity (CGI-S) scores, the key secondary endpoint of the Phase 3 study.

The systemic safety profile of SECUADO was consistent with what is known for sublingual asenapine.¹ The most commonly observed adverse reactions were extrapyramidal disorder, application site reaction, and weight gain.¹

Please click [here](#) for full Prescribing Information, including a 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).³

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. For information about Hisamitsu, visit www.hisamitsu.co.jp/english.

Contact:
Monica Lara
Noven Pharmaceuticals, Inc.
305-253-1916

¹ Secuado [prescribing information]. Miami, FL: Noven Therapeutics LLC; 2019.

² Citrome, L, Zeni CM, Correll CU. Patches: Established and Emerging Transdermal treatments in psychiatry. J Clin Psychiatry 2019;90(4):18nr12554.

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

###