

Tris Pharma Expands ADHD Portfolio with Acquisition of NextWave Pharmaceuticals

Tris ADHD Franchise Includes Quillivant XR[®] (methylphenidate HCl), QuilliChew ER[®] (methylphenidate HCl) and DYANAVEL[®] XR (amphetamine) Offering Multiple Treatment Options for Children and Adolescents with ADHD

NEWS PROVIDED BY

Tris Pharma, Inc. →

09:02 ET

MONMOUTH JUNCTION, N.J., Sept. 25, 2018 /PRNewswire/ -- Tris Pharma, Inc. (Tris), a pharmaceutical company focused on developing innovative technology-based therapeutic products that address unmet patient needs, today announced the acquisition of NextWave Pharmaceuticals (NextWave), a wholly owned subsidiary of Pfizer Inc. (Pfizer), including two key Attention Deficit Hyperactivity Disorder (ADHD) treatments. The acquisition further expands Tris' portfolio of products for the treatment of patients with ADHD. The agreement includes the acquisition of Quillivant XR, the first and only marketed extended-release oral liquid methylphenidate, and QuilliChew ER, the first and only extended-release methylphenidate chewable tablet, both of which are central nervous system (CNS) stimulants approved for the treatment of ADHD.

Please see important safety information for Quillivant XR and QuilliChew ER, including Boxed Warning about Abuse and Dependence, below.

Quillivant XR and QuilliChew ER were co-developed by NextWave and Tris, utilizing Tris' novel, proprietary LiquiXR[®] platform. In 2012, Pfizer acquired NextWave, and Tris continued to manufacture both products for Pfizer, prior to and after US Food and Drug Administration (FDA) approval.

"As co-developer of Quillivant XR and QuilliChew ER, we are excited to bring commercialization of these products in house and expand our ADHD portfolio," said Ketan Mehta, President and Chief Executive Officer, Tris. "To further support our newest acquisition, Tris is expanding our commercial footprint and building a world class medical affairs group."

"Our newest acquisition brings us one step closer to realizing our corporate mission, to develop and expand offerings to meet unmet needs for all patients," said Barry K. Herman, M.D., M.M.M., Tris' Chief Medical Officer. "With three treatment options for patients with ADHD, Tris now offers a broad, established product portfolio with both stimulant classes in the ADHD space."

DYANAVEL XR is the first liquid amphetamine for children 6 years and older with ADHD, launched by Tris in 2016. Please see important safety information for DYANAVEL XR, including Boxed Warning about Abuse and Dependence, below.

Important Safety Information for Quillivant XR and QuilliChew ER

Quillivant XR and QuilliChew ER are federally controlled substances (CII) because they can be abused or lead to dependence. Keep Quillivant XR and QuilliChew ER in a safe place to prevent misuse and abuse. Selling or giving away Quillivant XR or QuilliChew ER may harm others and is against the law. Tell your doctor if you or your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines, or street drugs.

Quillivant XR or QuilliChew ER should not be taken if you or your child are allergic to methylphenidate hydrochloride, or any of the ingredients in Quillivant XR or QuilliChew ER, or are taking or have taken within the past 14 days an antidepressant medicine called a monoamine oxidase inhibitor or MAOI.

The following have been reported with the use of methylphenidate hydrochloride and other stimulant medicines:

- **Heart-related problems:**
 - **Sudden death in patients who have heart problems or heart defects**
 - **Stroke and heart attack in adults**
 - **Increased blood pressure and heart rate**
 - Your healthcare provider should check you or your child's blood pressure and heart rate regularly during treatment with Quillivant XR or QuilliChew ER

- **Mental (psychiatric) problems:**
 - **New or worse behavior and thought problems**
 - **New or worse bipolar illness**
 - **May cause new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms**

- **Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon):**
 - Fingers or toes may feel numb, cool, painful, or may change color from pale, to blue, to red

Call your healthcare provider right away if you or your child have any:

- **Heart-related symptoms such as chest pain, shortness of breath, or fainting**
- **New or worsening mental (psychiatric) symptoms or new manic symptoms**
- **Signs of unexplained wounds appearing on fingers or toes while taking Quillivant XR or QuilliChew ER**

Quillivant XR or QuilliChew ER may not be right for you or your child. Tell your healthcare provider if:

- You or your child have, or have a family history of, heart problems, heart defects, or high blood pressure
- You or your child have mental problems, including psychosis (hearing voices, believing things that are not true, are suspicious), mania, bipolar illness, or depression, or a family history of suicide, bipolar illness, or depression
- You or your child have circulation problems in fingers and toes
- You or your child have phenylketonuria (PKU). QuilliChew ER contains phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with PKU or who are allergic to phenylalanine
- You are pregnant or plan to become pregnant. It is not known if Quillivant XR or QuilliChew ER will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant
- You are breastfeeding or plan to breastfeed. Quillivant XR or QuilliChew ER passes into your breast milk. You and your doctor should decide if you will take Quillivant XR or QuilliChew ER or breastfeed

What should I avoid while taking Quillivant XR or QuilliChew ER?

Quillivant XR and QuilliChew ER should not be taken with MAOI medicines or if you stopped taking an MAOI in the last 14 days. Do not drink alcohol while taking Quillivant XR or QuilliChew ER. This may cause a faster release of your methylphenidate dose.

What are the possible side effects of Quillivant XR or QuilliChew ER?

Quillivant XR or QuilliChew ER may cause serious side effects, including:

- See "**What is the most important information I should know about Quillivant XR or QuilliChew ER?**" for information on reported heart and mental problems.

Other serious side effects include:

- Painful and prolonged erections (priapism) have occurred with methylphenidate. If you or your child develop priapism seek medical help right away. **Because priapism can cause long-lasting damage, it should be checked by a healthcare provider right away**
- Slowing of growth (height and weight) in children

Common side effects include:

- Decreased appetite
- Trouble sleeping
- Nausea
- Vomiting
- Indigestion
- Stomach pain
- Weight loss
- Anxiety
- Dizziness
- Irritability
- Mood swings
- Fast heart beat
- Increased blood pressure

These are not all the possible side effects of Quillivant XR and QuilliChew ER.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see Full Prescribing Information for Quillivant XR and QuilliChew ER, including Medication Guides, at www.QuillivantXR.com and www.QuilliChewER.com, respectively.

Important Safety Information for DYANAVEL XR

DYANAVEL XR is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep DYANAVEL XR in a safe place to prevent misuse and abuse. Selling or giving away DYANAVEL XR may harm others, and is against the law.

Tell your physician if you, your child, or any family members have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

DYANAVEL XR should not be taken if you or your child are allergic to amphetamine or any of the ingredients in DYANAVEL XR, or are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI.

DYANAVEL XR can cause serious side effects. Tell the doctor:

- if you or your child have heart problems or heart defects, high blood pressure, or a family history of these problems. This is important because sudden death has occurred in children and adolescents with heart problems or defects, and sudden death, stroke, and heart attack have happened in adults. Your doctor should check you or your child carefully for heart problems before starting DYANAVEL XR. Since increases in blood pressure and heart rate may occur, the doctor should regularly check these during treatment. **Call the doctor right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting while taking DYANAVEL XR.**
- if you or your child have mental problems, or a family history of suicide, bipolar illness, or depression. This is important because new or worsening behavior and thought problems or bipolar illness may occur. New symptoms such as seeing or hearing things that are not real, believing things that are not true, being suspicious, or having new manic symptoms may occur. **Call the doctor right away if there are any new or worsening mental symptoms during treatment.**
- if you or your child have circulation problems in fingers and toes (called peripheral vasculopathy, including Raynaud's phenomenon). Fingers or toes may feel numb, cool, painful, sensitive to temperature, and/or change color from pale, to blue, to red. **Call the doctor right away if any signs of unexplained wounds appear on fingers or toes while taking DYANAVEL XR.**
- if your child is having slowing of growth (height and weight); DYANAVEL XR may cause this serious side effect. Your child should have his or her height and weight checked often while taking DYANAVEL XR. The doctor may stop treatment if a problem is found during these check-ups.
- if you or your child are pregnant, breastfeeding, or plan to become pregnant or breastfeed.

Common side effects of amphetamine products include:

- dry mouth
- decreased appetite
- weight loss
- stomach pain
- nausea
- trouble sleeping
- restlessness
- extreme mood changes
- dizziness
- increased heart rate

Talk to your doctor if you or your child have any side effects that bother you or do not go away.

Avoid drinking alcohol while taking DYANAVEL XR.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see Full Prescribing Information for DYANAVEL XR, including Boxed Warning about Abuse and Dependence, and Medication Guide, at www.DyanavelXR.com.

About ADHD

ADHD is one of the most common neurodevelopmental disorders characterized by an ongoing pattern of inattention and/or hyperactivity and impulsivity. These behaviors can interfere with functioning or development. According to the Centers for Disease Control and Prevention's 2011 data, 11 percent of children aged four to 17 years in the U.S. have received an ADHD diagnosis at some point in their life.

About Tris Pharma

Tris Pharma is a fully integrated pharmaceutical company focused on the development of innovative medicines that address unmet patient needs. Tris has pioneered the delivery of sustained release in the liquid, chewable, orally disintegrating tablet, and strip dosage forms that benefit a wide variety of patients and their unique needs. Tris' research, manufacturing and commercial facilities are located in Central New Jersey.

For more information, please visit www.trispharma.com

DYANAVEL is a registered trademark of Tris Pharma, Inc.

Quillivant and QuilliChew are registered trademarks of NextWave Pharmaceuticals, Inc.

© 2018 Tris Pharma, Inc. All rights reserved.

QUI-0010 09/18

SOURCE Tris Pharma, Inc.

Related Links

<http://trispharma.com/>