6 Month OL Study to Evaluate the Safety, Tolerability and Efficacy of Methylphenidate HCl ERCT in Children With ADHD.

ClinicalTrials.gov Identifier: NCT03580005

Recruitment Status : Not yet recruiting
First Posted : July 9, 2018
Last Update Posted : July 9, 2018
See **Contacts and Locations**

Sponsor:
Pfizer
Information provided by (Responsible Party):
Pfizer

Study Description
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Brief Summary:
6-month open label study to evaluate the safety, tolerability and efficacy of methylphenidate HCl ERCT in children with ADHD

Condition or disease
Attention Deficit Hyperactivity Disorder (ADHD)

Detailed Description:
6 month open label study to evaluate the safety, tolerability and efficacy of methylphenidate HCl ERCT in preschool aged children with ADHD who participated in study B7491017 or B7491020.

Study Design
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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	88 participants
Intervention Model:	Single Group Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment

Official Title:	A Phase 4, 6-month Open-label Extension Study To Evaluate The Safety, Tolerability And Efficacy Of Quillichew (Methylphenidate Hydrochloride (Hcl)) Extended Release Chewable Tablets (Erct) In Children With Attention Deficit Hyperactivity Disorder (Adhd) Who Participated In Study B7491017 Or Study B7491020.
Estimated Study Start Date :	October 31, 2018
Estimated Primary Completion Date :	October 12, 2021
Estimated Study Completion Date :	October 12, 2021

Resource links provided by the National Library of Medicine
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

Drug Information available for: Methylphenidate Methylphenidate hydrochloride

U.S. FDA Resources

Arms and Interventions
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Arm	Intervention/treatment
methylphenidate HCl ERCT methylphenidate HCl ERCT	Drug: methylphenidate HCl ERCT methylphenidate HCl ERCT

Outcome Measures
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Primary Outcome Measures :

1. Safety-incidence of treatment emergent adverse events [Time Frame: 6 months]

   incidence of treatment emergent adverse events

Eligibility Criteria
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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	4 Years to 5 Years (Child)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

1. Male or female child who participated in B7491017 or B7491020.

2. Signed and dated informed consent provided by the subject's parent/legal and assent of the child (as applicable).
3. Willing and able to comply with scheduled visit, treatment plan, laboratory tests and other study procedures.
4. Sitting systolic or diastolic blood pressure (BP) <95th percentile for age, sex, and height.

Exclusion Criteria:

1. Clinically significant AEs or SAEs related to investigational product while participating in study B7491017 or study B7491020 that would preclude treatment with methylphenidate HCl ERCT.
2. Other acute or chronic medical or psychiatric condition that would make the patient inappropriate for entry.
3. Use of prohibited concomitant treatments.
4. Poor compliance with investigational product or study procedures.

Contacts and Locations
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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03580005***

Contacts

Contact: Pfizer CT.gov Call Center 1-800-718-1021 ClinicalTrials.gov_Inquiries@pfizer.com

Sponsors and Collaborators
Pfizer
Investigators

Study Director: Pfizer CT.gov Call Center Pfizer
More Information
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Additional Information:
To obtain contact information for a study center near you, click here. EXIT
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Responsible Party:	Pfizer
ClinicalTrials.gov Identifier:	NCT03580005 History of Changes
Other Study ID Numbers:	B7491019
First Posted:	July 9, 2018 Key Record Dates
Last Update Posted:	July 9, 2018
Last Verified:	June 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	Yes
Plan Description:	Information relating to our policy on data sharing and the process for requesting data can be found at the following link: http://www.pfizer.com/research/clinical_trials/trial_data_and_results/data_requests
URL:	http://

Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

Attention Deficit Disorder with Hyperactivity	Methylphenidate
Hyperkinesis	Central Nervous System Stimulants
Attention Deficit and Disruptive Behavior Disorders	Physiological Effects of Drugs
Neurodevelopmental Disorders	Dopamine Uptake Inhibitors
Mental Disorders	Neurotransmitter Uptake Inhibitors
Dyskinesias	Membrane Transport Modulators
Neurologic Manifestations	Molecular Mechanisms of Pharmacological Action
Nervous System Diseases	Dopamine Agents
Signs and Symptoms	Neurotransmitter Agents