The Jazz Piccolo Study (Piccolo means "little one" in Italian) is investigating the safety and effectiveness of cannabidiol (or CBD oral solution) in infants (2 years of age and younger) with Tuberous Sclerosis Complex (TSC), Lennox-Gastaut Syndrome (LGS) or Dravet Syndrome (DS) who experience inadequately controlled seizures.

TSC, LGS and DS are rare, early-onset epilepsies with life-long impact. Current treatment options for seizures associated with these conditions have substantial limitations, including poor seizure control and numerous side effects. Studies have shown that poor seizure control leads to additional health issues and a lower quality of life for those affected. Therefore, early treatment and control of seizures may be critical in improving the outcomes for children with these conditions.

For more information on the Jazz piccolo study please visit our website

www.JazzPiccoloStudy.com

Or contact the nearest participating study site:

Site Specific Details to be Added Here

Principal Investigator:
Xxxxx Xxxxxx

Clinical Study Coordinator:
Xxxxx Xxxxxx

Telephone: +X XXX.XXX.XXXX
Email: xxxxx@xxxx.xxx

Jazz Pharmaceuticals

piccolo STUDY

THE JAZZ PICCOLO STUDY

Is your child suffering from seizures and less than 2 years of age?

If so, your child may qualify for the Jazz Piccolo Study!

WHAT DO I NEED TO KNOW ABOUT THE STUDY?

The Jazz Piccolo Study will involve up to 10 visits to a study clinic and 12 telephone calls and will include a:

- 4 week screening/baseline period
- 52-week treatment period
- 10-day taper following completion of the 52-week treatment regiment
- 4-week safety/follow-up period

Children who are eligible and participate in the Jazz Piccolo Study will receive the investigational drug, as well as study-related visits, tests and assessments, at no cost. Participants can stop taking part in the clinical trial at any time without giving a reason. Caregivers of participants may also be reimbursed for some study-related expenses, such as costs associated with travel and hotels.

The drug being investigated in this study is a cannabidiol (or CBD oral solution) that is taken twice daily and has been approved by the U.S. Food and Drug Administration for the treatment of seizures associated with LGS, DS, or TSC in patients 1 year of age and older. The cannabidiol in the investigational drug (known as GWP42003-P) is extracted from cannabis plants with a minimal amount of the component which causes a 'high' (known as tetrahydrocannabinol or THC).

Here is a list of key Inclusion/Exclusion Criteria to participate in the study:

KEY INCLUSION CRITERIA

- Children with confirmed:
  - Tuberous Sclerosis Complex: 1 month to < 2 years of age; or
  - Dravet Syndrome: 1 year to < 2 years of age, or
  - Lennox-Gastaut Syndrome: 1 year to < 2 years of age
- Has seizures not adequately controlled through their current antiseizure medications
- Currently receiving 1 or more antiseizure medications
- A suitable Video EEG or VEEG for confirmation of diagnosis; VEEG is short for a video EEG (electroencephalograph) which records a patient's experience on video while an EEG test records brainwave function

KEY EXCLUSION CRITERIA

- Clinically significant unstable medical condition other than epilepsy
- Clinically significant symptoms or illness which could affect the seizure frequency
- Has undergone surgery for epilepsy within 6 months
- Significantly impaired hepatic (liver) function

  Currently using recreational or medicinal cannabis, cannabinoid-based medications or CBD