A Long-term Extension (LTE) Study of Guselkumab in Pediatric Participants

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 3 years and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Must have completed the dosing planned in the primary pediatric guselkumab study
- Must have received benefit from continued guselkumab therapy in the opinion of the investigator
- Before enrollment, a participant must be either: (a) Not of childbearing potential, OR (b) Of childbearing potential and not sexually active, practicing abstinence or a highly effective method of contraception and agrees to remain on a highly effective method while receiving study intervention and until 12 weeks after the last dose - the end of relevant systemic exposure
- Parent(s) (or their legally acceptable representative) must sign an informed consent form (ICF) indicating that he or she understands the purpose of, and procedures required for, the study and is willing to allow the child to participate in the study. Assent is required from participants who are capable of understanding the nature of the study, typically those aged 7 years and older, to ensure their willingness to participate. An adolescent who provides assent will have the opportunity to sign an adult ICF upon reaching the age of majority, thereby affirming their understanding of the study's purpose and procedures, as well as their willingness to participate.

Exclusion Criteria:

- Participant is greater than or equal to (>=) 18 years of age and resides in a country where 2 years have elapsed post marketing authorization for the respective adult indication
- Participant is <18 years of age and resides in a county where 2 years have elapsed post marketing authorization for the respective pediatric indication
- Are pregnant, nursing, or planning pregnancy or fathering a child
- Have taken any disallowed therapies before the planned first long-term extension (LTE) dose of study intervention
- Employee of the investigator or study site, with direct involvement in the proposed study or other studies under the direction of that investigator or study site, as well as family members of the employees or the investigator
- Any condition for which, in the opinion of the investigator, participation would not be in the best interest of the participant or that could prevent, limit, or confound the protocol-specified assessments

Conditions & Interventions

Interventions:
DRUG: Guselkumab
Conditions:
Crohns Disease, Colitis, Ulcerative, Arthritis, Psoriatic, Arthritis, Juvenile

More Information

Description:
The purpose of this study is to evaluate long-term safety of subcutaneous guselkumab in pediatric participants with moderately to severely active ulcerative colitis, or moderately to severely active Crohn's disease, or juvenile psoriatic arthritis (jPsA).

Contact(s): Megan Megan Quinlan-Waters - Megan.Quinlan-Waters@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: PHASE3
IRB Number:
System ID: NCT06663332