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Efficacy and safety of oral BT-11 in moderate to severe Crohn's disease

Submission date 08/07/2021	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 03/08/2021	**Overall study status** Completed	
Last Edited 03/08/2021	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Crohn's Disease (CD) is an inflammatory disorder of the intestines that can affect all layers of the bowel walls. As a result of genetic and environmental factors, the cells lining the intestine can become disrupted, causing the immune system to react and damage the tissue. Unlike with normal immune responses, immune responses in CD do not resolve naturally. Therefore, CD patients are treated with steroids, immunosuppressants and biologics that dampen the immune system. However, these treatments do not just affect the digestive system, but also cause many side effects including increased risk of infections and cancers. In addition, current treatments do little to restore the balance in the immune system through regulatory responses, which can naturally counteract damaging inflammatory responses. The main aim of this study is to assess the effectiveness and safety of a new oral treatment BT-11 in mild to moderate CD.

Who can participate?
Patients aged 18 to 75 years with a diagnosis of mild to moderate CD for at least 3 months

What does the study involve?
Participants are randomly allocated to one of two treatment groups (BT-11 or placebo [dummy drug]). After informed consent, all participants undergo an endoscopy, blood tests and other measurements to determine characteristics and severity of disease. If eligible, participants begin 12 weeks of treatment according to the assigned treatment group. At the end of the 12 weeks, participants undergo an endoscopy to observe changes in the health of the colon in addition to changes in biomarkers, histopathology, and patient-reported outcomes, such as stool frequency and rectal bleeding.

What are the possible benefits and risks of participating?
Potential benefits of participation include contributing to the development process in an area of unmet therapeutic need. BT-11 has no known dose-limiting side effects. It may offer an alternative for future patients with CD. BT-11 may decrease the production of inflammatory mediators and increase anti-inflammatory molecules in the digestive tract. Participants in both BT-11 and placebo groups may experience benefit from more frequent assessments by clinical experts for management of CD. To minimize risk, women planning to become pregnant are not eligible for the study and pregnancy tests are performed throughout the study. Endoscopy with

biopsy is generally well tolerated as in standard clinical care. However, risks include discomfort, bleeding, or in rare cases perforation.

Where is the study run from?
About 45 sites will participate in Europe and in North America in the following countries: Belarus, Poland, Bosnia and Herzegovina, Croatia, Serbia, Georgia, Ukraine, Hungary, United States of America, Netherlands, Austria, Belgium, Turkey, Czech Republic

When is the study starting and how long is it expected to run for?
April 2021 to January 2022

Who is funding the study?
Landos Biopharma, Inc. (USA)

Who is the main contact?
Jyoti Chauhan, jyoti@landosbiopharma.com

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2019-000824-17

ClinicalTrials.gov (NCT)
NCT03870334

Protocol serial number
BT-11-202

Study information

Scientific Title
A randomized, placebo-controlled, double-blind, multicenter study to evaluate efficacy and safety of oral BT-11 in moderate to severe Crohn's disease

Acronym
BT-11-202

Study objectives
To evaluate the efficacy and safety of oral BT-11 induction compared to placebo in subjects with moderate to severe CD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/04/2021, Advarra IRB (6940 Columbia Gateway Drive, Suite 110 Columbia, Maryland 21046; +1410-884-2900; Kaitlyn.Halom@advarra.com), ref: BT-11-202

Study design
Phase 2 randomized placebo-controlled double-blind parallel-group multicenter induction study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Crohn's Disease

Interventions
Subjects will be randomized to receive BT-11 1,000 mg once-daily or placebo (control) for 12 weeks in the form of an orally swallowed tablet. Patients will be randomized in a 1:1 ratio in a centralized manner, stratified by prior exposure to biologic therapy for CD (yes/no; exposed population limited to 50% of total sample) and corticosteroid use at baseline (yes/no).

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Omilancor (BT-11)

Primary outcome(s)
Clinical remission rate defined by a CDAI score of <150 measured at 12 weeks using patient records

Key secondary outcome(s))
1. Clinical response measured by a CDAI reduction from baseline (≥100 points or CDAI <150) at 12 weeks
2. Endoscopic remission measured by SES-CD OF 0-2 or SES-CD ≤4, a ≥2-point improvement over baseline, and no sub-score >1 at 12 weeks

3. Histologic remission measured by Geboes score <2B.1 (with absence of neutrophils in lamina propria) at 12 weeks
4. Endoscopic response measured by SES-CD score (proportion of subjects achieving clinical remission defined as 50% reduction from baseline in SES-CD score at 12 weeks)

Completion date
31/01/2022

Eligibility

Key inclusion criteria
1. Subjects aged 18 to 75 years with a diagnosis of CD for at least 3 months
2. Moderately to severely active CD as defined by: a CDAI score of 220 450, and an SES-CD scored ≥6 (≥4 for isolated ileitis) (centrally read)
3. Prior biologic must have stopped at least 8 weeks before study (or within 4 weeks prior to randomization, if no detectable drug levels by validated or commercial assay) and previous biologic treatment failure is limited to 1 class of biologic (if applicable)
4. 5 -aminosalicylates (max 4.8 g/day) and oral corticosteroids (max 20 mg/day prednisone or equivalent) must be stable for the duration of the 12-week induction period

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Ulcerative colitis
2. Imminent risk of ileocolectomy, symptomatic bowel stricture, ostomy or ileoanal pouch, stenoses, or short gut syndrome
3. Recent (within 2 months) abscess, unless drained and treated at least 6 weeks before randomization
4. History of bowel resection or diversion within 3 months prior to screening
5. Use of apheresis ≤2 weeks prior to screening; treatment with an immunosuppressant within 25 days prior to randomization
6. Known current bacterial or parasitic pathogenic enteric infection, live virus vaccination within 12 weeks of screening

Date of first enrolment
06/05/2021

Date of final enrolment
31/10/2021

Locations

Countries of recruitment
Austria

Belarus

Belgium

Bosnia and Herzegovina

Bulgaria

Czech Republic

Netherlands

Poland

Serbia

Slovakia

Spain

Türkiye

Ukraine

United States of America

Study participating centre
IHS Health
445 W Oak St.
Kissimmee
United States of America
34741

Study participating centre
Valencia Medical Research
9804 SW 40th St.

Miami
United States of America
33165

Study participating centre
Allameh Medical Corp
25982 Pala
Mission Viejo
United States of America
92691

Study participating centre
Woodholme Gastroenterology Associates
802 Landmark Drive, Suite 120
Glen Burnie
United States of America
21061

Study participating centre
GI Clinical Research Enterprise
1161 21st Avenue South, MCN A-4103C
Nashville
United States of America
37232

Study participating centre
GCP Clinical Research
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United States of America
33609

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Sponsor information

Organisation
Landos Biopharma, Inc.

Funder(s)

Funder type
Industry

Funder Name
Landos Biopharma, Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date