Summary: A phase 3, multicenter, placebo-controlled, randomized, double blind study to evaluate the safety and efficacy of PROCHYMAL (ex vivo cultured adult human mesenchymal stem cells) intravenous infusion for the induction of remission in subjects experiencing treatment-refractory moderate-to-severe crohn's disease.

These mesenchymal stem cells are isolated from the bone marrow of 4 healthy adult donors ages 18-30.

Inclusion Criteria:

1. Subject must be 18 to 70 years of age.
2. Females of childbearing age must be non-pregnant, non-breastfeeding. Males and females must use adequate contraception.
3. Subjects must have crohn's disease that has been endoscopically or radiographically confirmed to be active within the 60 days prior to screening or during screening.
4. Subject must have a CDAI between 250 and 450.
5. Subject must have had, for EACH of the following three treatment categories, either an inadequate or lost response to a drug in that category within the past 24 months or DOCUMENTD INTOLERANCE TO A DRUG IN THAT CATEGORY AT ANY TIME.

Note: subjects may currently be receiving steroids or immunomodulators at the time of enrollment.

- Steroids
    a. Oral prednisone taper that began at a dose of > 40mg/d with continuous steroid use at any dose for at least 4 weeks.

- Immunosuppressants
    a. Azathioprine > 2mg/kg/d for at least 12 weeks, or
    b. 6-mercaptopurine> 1 mg/kg/d for at least 12 week, or
    c. Methotrexate > 15mg/week for at least 12 weeks

- Biologics
    a. Infliximab > 5mg/kg for at least 8 weeks, or
    b. Adalimumab. 40 mg every other week for at least 8 weeks, or
    c. Certolizumab pegol > 400 mg monthly for at least 8 weeks.

Other Inclusion Criteria:

1. Subject must have a CRP of at lest 5mg/l
2. Subject must have a body mass between 40 and 150kg.
3. Subject must have crohn's ilocolitis, colitis, or ileitis.
4. Subject may be receiving oral 5-ASAs, corticosteroids, antibiotics, azathioprine, 6-mp, methotrexate, or any similar drugs at the time of enrollment.
5. Subject must have adequate renal function.
6. Subject must have documented negative TB skin test.

Exclusion Criteria:

1. Subject has evidence of substance abuse within 6 months.
2. Subject has as active infection with HIV or hepatitis B or C.
3. Subject has had surgery or trauma within 6 weeks.
4. Subject has a known allergy to CT contrast agents.
5. Subject has a known allergy to bovine or porcine products.
6. Subject has evidence of symptomatic fibrostenotic obstructive Crohn's disease.
7. Subject has a seton in place
8. Subject has received any antibody, protein, or biologic therapy during the 90 day prior to study screening.
9. Subject has received prednisone at a dose greater than 20mg/d at any time 28 days prior the enrollment in study.
10. Subject has a permanent colostomy or ileostomy.
11. Subject has known or suspected short bowel syndrome.
12. Subject requires parenteral or total parenteral nutrition.
13. Subject has chemistry or hematology lab values that are clinically significant.
14. Subject has evidence of active malignancy or history of active malignancy that has not been in remission for at least 5 years.
15. Subject has cardiopulmonary disease that in the opinion of the Investigator is either unstable or severe enough to justify exclusion from this study.
16. Subject has an unstable arrhythmia. Subject has positive stool cultures for pathogens.
17. Subject has low grade or high-grade colonic mucosal dysplasia.

This criterion is not all-inclusive, for more information please contact:

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