**Title of Study: A Phase 2 double-blind placebo-controlled study investigating the safety and efficacy of EDP1815 in the treatment of patients hospitalized with SARS-CoV-2 Infection**

The **purpose of the research** is to study if EDP1815 is safe and helps treat people with COVID-19.

This drug is a strain of bacteria that is normally found in the human gut and is designed to lower inflammation in the body.

|  |  |  |  |
| --- | --- | --- | --- |
| **INCLUSION/EXCLUSION CRITERIA** | | | |
| **Inclusion** |  | | **Exclusion** |
| 1. COVID + at screening by PCR 2. Admitted < 36 hours 3. Age 18-65 4. Require supplemental oxygen at baseline | 1. contraindication/AE to *P histicola* or any excipients 2. Chronic hypoxia or significant chronic respiratory dz 3. ICU or CPAP 4. Primary immunodeficiency 5. On chronic immunosuppressant 6. CKD4/5 or GFR<30 7. Chronic liver dz with ALT, AST> 5x ULN 8. Preexisting significant GI tract dz affecting absorption 9. Significant cardiac dz (unstable angina, acute MI) <6 wks prior to screening 10. GI signs/sxs = CTCAE v5.0 GI d/o, grade 3 or 4 |
|  | | | |
| **Day 1, 4 and 7 LABS** | | **Potential side effects** | |
| CBC, CMP Ferritin, D-Dimer, LDH, CRP, Troponin, , pregnancy test for women of childbearing potential | | * headache diarrhea * Pain or bruise from blood draw | |
|  | | | |
|  | | **Treatment duration** | |
| * **Total 14 days of EDP1815 or placebo** * **1;1 EDP1815/placebo** | |
| **Patient can be discharged earlier. Patient can take the remaining study medication at home.**  **Study team will contact patient via phone.** | | **Contact info:**  **Dr Sugeet Japal**  **Dr Ting-Yu Jih**  **Dr Jared Radbel**  **Fei Chen RN 732-318-1411 (24 hrs.) text ok** | |

No prohibited concomitant medications pertaining to treatment/management of COVID19