REPAVID-22

A phase 3, multinational, randomized, double-blind, placebo-controlled trial (NCT05254990) is ongoing to evaluate the efficacy and safety of oral reparixin as an add-on therapy to the standard of care to limit disease progression in adults hospitalized with community-acquired pneumonia (CAP)

Inclusion criteria

- Signed informed consent
- Adults ≥18 years old
- Participants hospitalized for clinically suspected CAP, defined as the occurrence within 48 hours from hospital admission of
  - ≥1 of the following signs/symptoms: dyspnea, cough, purulent sputum, crackles (rales) and/or rhonchi
  - Body temperature >38°C or <36°C (before or during admission) or leukocytosis (>local ULN)
  - New/Increased pulmonary infiltrate(s) by chest imaging
- Need for noninvasive supplemental oxygen
- SpO_2 <92% at room air *or* PaO_2/FiO_2 <300 mmHg (or SpO_2/FiO_2)
- Females of childbearing potential who are sexually active must be willing not to get pregnant within 30 days after their last dose and must agree to ≥1 reliable method of contraception. For all female subjects of childbearing potential, a pregnancy test result must be negative before first drug intake

Primary endpoint

- Mortality or requirement for invasive mechanical ventilation, or extracorporeal membrane oxygenation, by Day 28

Treatment regimen

- Participants will be randomized (1:1) to receive oral reparixin 1200 mg or placebo by mouth three times daily for up to 21 days and followed when they are discharged or if they are still hospitalized at Day 28 and up to Day 180
  - Participants will stop receiving reparixin or placebo before Day 21 if they are discharged from the hospital or receive invasive mechanical ventilation or extracorporeal membrane oxygenation
- Antimicrobial treatment and supportive care will be provided according to clinical status and standard of care

Reparixin is an investigational drug that is not approved for use in any country and is currently being investigated in clinical trials.
Contact usmedinfo@dompe.com for any questions.
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REPAVID-22 Phase 3 Clinical Trial

Prohibited medications

The following medications **should not be used** from within 5 half-lives of screening to Day 28:

- Treatment with any not authorized investigational agent (except for off-label use of anti–COVID-19 agents)
- T cell or B cell–targeted therapies, interferons, or convalescent plasma
- CYP2C9 inducers (eg, rifampin, carbamazepine, aprepitant, bosentan, phenobarbital, St. John's Wort) or CYP2C9 inhibitors (eg, amiodarone, fluconazole, miconazole, oxandrolone, capecitabine, cotrimoxazole, etravirine, fluvastatin, fluvoxamine, metronidazole, sulfinpyrazone, tigecycline, voriconazole, zafirlukast)

Exclusion criteria

- Treatment with invasive mechanical ventilation or extracorporeal membrane oxygenation
- Hepatic dysfunction: ALT or AST > 5× ULN; history of chronic hepatic disease (defined as Child-Pugh class B or C)
- Renal dysfunction: estimated glomerular filtration rate (eGFR) <50 mL/min/1.73 m^2 or end-stage renal disease on renal replacement therapy
- Current use of >2 immunosuppressive medications or immunosuppression status (AIDS, aplastic anemia, asplenia, systemic chemotherapy within the past 3 months, neutropenia [ANC <local LLN], solid organ or bone marrow transplant recipient)
- Anticipated discharge from the hospital or transfer to another hospital within 72 hours of screening
- History of: hypersensitivity to ibuprofen or other nonsteroidal anti-inflammatory drugs (NSAIDs); or documented allergy/hypersensitivity to >1 medication belonging to the class of sulfonamides (hypersensitivity to sulfanilamide antibiotics; eg, sulfamethoxazole does not qualify for exclusion); or allergy to reparixin or any component of the IMP formulation; or lactase deficiency, galactosemia, or glucose-galactose malabsorption; or gastrointestinal bleeding or perforation due to previous NSAID therapy or recurrent peptic ulcer/hemorrhage
- Active bleeding or bleeding diathesis (excluding menses), prior intracranial hemorrhage
- Participation in other interventional clinical trials
- Clinical condition not compatible with oral administration of the study drug
- Pregnant or lactating women or women of childbearing potential and fertile men who do not agree to use ≥1 primary form of contraception for the duration of the study
- Current hospital stay >72 hours
- Complicated CAP-associated conditions such as fungal pulmonary infection, tuberculosis, abscess, empyema, significant bilateral pleural effusion, or massive pulmonary embolism

AIDS, acquired immunodeficiency syndrome; ALT, alanine transaminase; ANC, absolute neutrophil count; AST, aspartate aminotransferase; COVID-19, coronavirus disease 2019; CYP, cytochrome P450; FiO_2, fraction of inspired oxygen; IMP, investigational medicinal product; LLN, lower limit of normal; NSAID, nonsteroidal anti-inflammatory drug; PaO_2, partial pressure of arterial oxygen; SpO_2, oxygen saturation; ULN, upper limit of normal.

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