Current proposed primary and secondary objectives for CORE protocol

Yazdan Yazdanpanah
Primary objective

To evaluate the **clinical efficacy**, as assessed by time to lesion resolution, of treatment plus SOC versus placebo plus SOC for patients with monkeypox.

“Lesion resolution is both an important patient-centered outcome and an important public health outcome for onwards transmission.”

For outpatients and hospitalized patients.
Secondary objectives

To evaluate the clinical efficacy of treatment plus SOC versus placebo plus SOC in patients with monkeypox as assessed by:

1. Mortality (all -cause mortality)

2. Clinical severity
   - Hospitalisations (Important patient centered and health system outcome. Easy to measure); only outpatients
   - Complications (Important patient-centered outcome and important health system outcome to prepare; but definitions should be clear and staff trained); outpatients and inpatients

3. Duration of symptoms and signs (Collection of symptoms and signs can be useful to understand the clinical characterization, however, will require intensive data collection)
Secondary objectives

4. To evaluate the **safety** of treatment plus SOC relative to placebo plus SOC in patients with monkeypox.
Exploratory objectives

1. To explore **viral trajectories** in a subgroup of patients (daily sampling is labor intensive and likely only to be done for hospitalized patients)

2. To understand **lesion characteristics** (body regions involved; lesion count)