Imusil

Clinical Evidence

Study Title

- **A Prospective, Randomized, Multi-center, Open-label, Interventional Study to Evaluate the Safety and Efficacy of Imusil® (Kutki Extract 200 mg + Guduchi extract 60 mg +Amla extract 60 mg) tablet in Treatment of Adult Subjects with mild COVID-19.**

- **Study objectives:** To observe and evaluate the efficacy and safety of Imusil®- a herbal supplement on mild COVID-19 subjects.

End points

- **Efficacy:**
- Rate of SARS-CoV2 RT-PCR negativity and changes in CT value in nasopharyngeal and/or oropharyngeal swab at Day 4 and Day 8
- Proportion of subjects with a 2-point decrease in ordinal scale (as recommended by WHO) at Day 4 and Day 8
- Changes in blood inflammatory indexes for CRP, Interleukin IL-6, and D-Dimer at Day 4 and Day 8
- **Safety:**
- Adverse events

Investigator	Name of Site	Site Address
Dr Mohammed Zaki Siddiqui	Maharani Laxmi Bai Medical College & Associated Hospital	MLB Medical College, Covid Hospital PMSSY Block, Jhansi UP 284128, India
Dr P Raghavendra Reddy	Renova Neelima Hospitals	Renova Neelima Hospitals, Opp. Voltas company, Sanathnagar, Hyderabad-500018, Telangana state, India
Dr. Dilip Kadam	Care Multispecialty Hospital	Care Multispecialty Hospital Kotle Arcade, Pune-Nagar Road, Wagholi-Pune-412207

Study groups

- The study was planned to be conducted on 100 subjects.
- Eligible 100 subjects were enrolled to receive Imusil® (Kutki Extract 200 mg + Guduchi extract 60 mg +Amla extract 60 mg) tablet plus Standard of Care (SOC) or Standard of care.
- **Group 1:** Imusil® (Kutki Extract 200 mg + Guduchi extract 60 mg +Amla extract 60 mg) tablet was administered at a dose of one tablet four times per day for 7 days plus Standard of Care (SOC) – 50 subjects
- **Group 2:** Standard of Care (SOC) was provided for 7 days - 50 subjects

Inclusion criteria

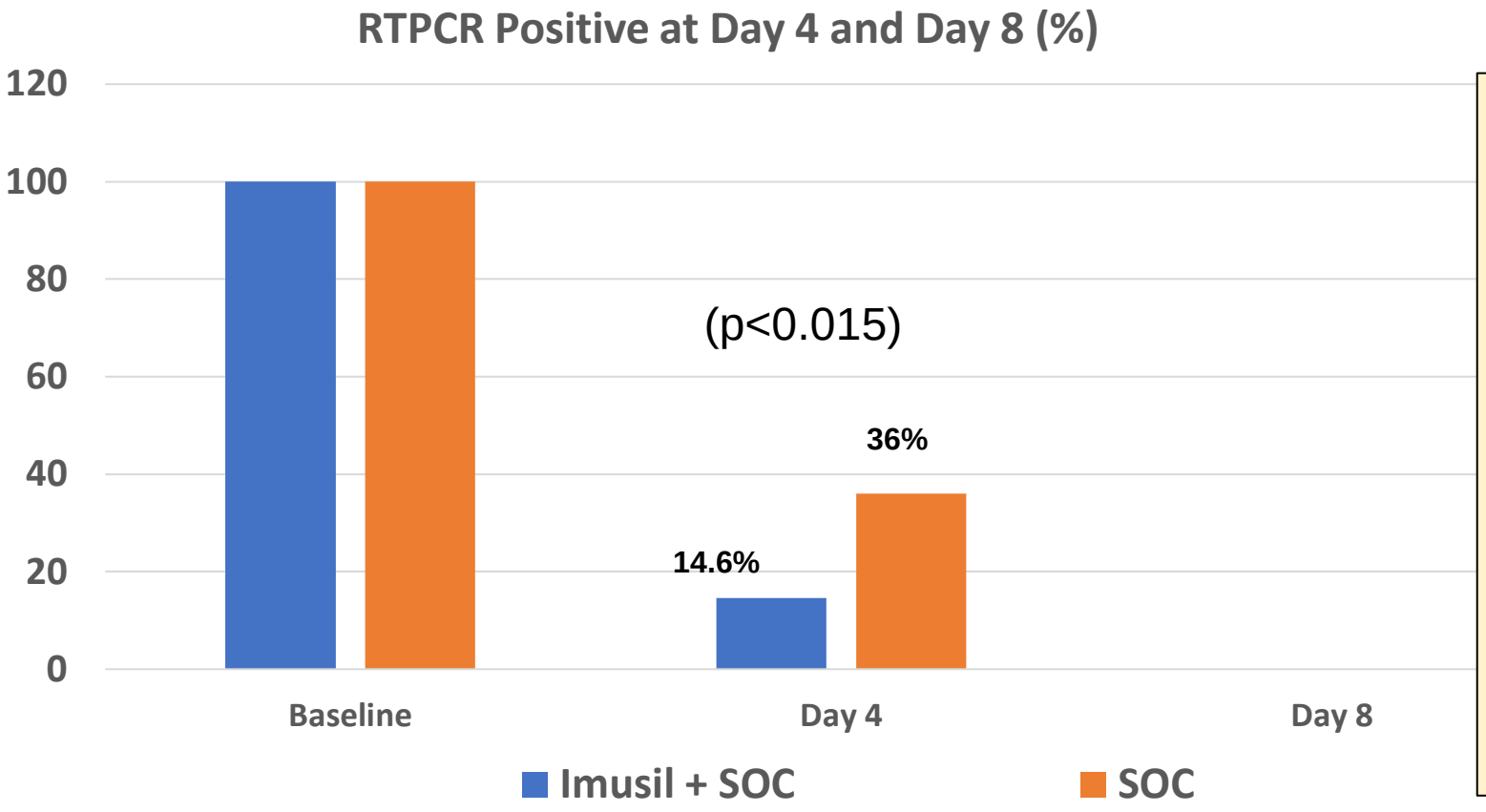
1. Male or female subjects of ≥18 to 60 years of age both inclusive
2. Subjects willing to give informed consent and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures.
3. Confirmed case of COVID-19 infection by RT-PCR and mild (without any non-invasive ventilation or high flow oxygen or assisted ventilation) cases of COVID-19. Scores of 2-3 on the WHO Eight point Ordinal Scale
4. Time interval between symptoms onset and randomization of no more than 2 days
5. One or more of the following symptoms:

- Fever of ≥100.4°F
- Headache
- Diarrhea
- Cough
- Nasal congestion
- Loss of smell
- Sore throat
- Malaise
- Loss of taste

Results: SARS-CoV$_2$ RT-PCR test

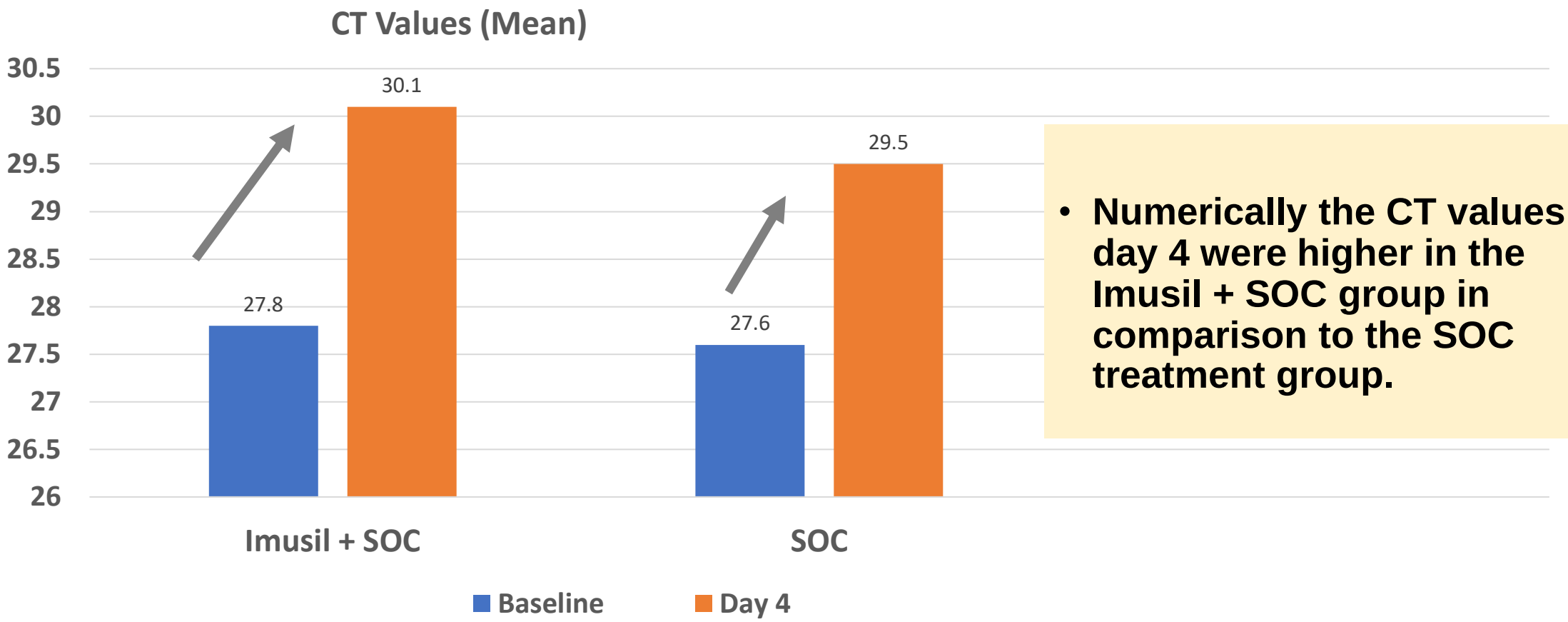
- At baseline, all subjects were SARS-CoV2 RT-PCR positive in both treatment arms.
- By day 4, 7 (14.6%) subjects were positive, and 41 (85.4%) subjects were negative in the Imusil®+SOC treatment arm.
- But in the SOC treatment arm, by day 4, 18 (36.0%) subjects were found positive, and 32 (64.0%) subjects were found negative.
- There were no SARS-CoV2 RT-PCR positive subjects in both treatment arms by the end of the study at day 7.

Results: SARS-CoV2 RT-PCR test



- **Rate of SARS-CoV2 RT-PCR negativity in nasopharyngeal and/or oropharyngeal swabs on Day 4 and Day 8 were evaluated which showed Imusil®+SOC arm improved faster and quicker than the SOC arm.**

Results: RTPCR CT values



- **Numerically the CT values on day 4 were higher in the Imusil + SOC group in comparison to the SOC treatment group.**

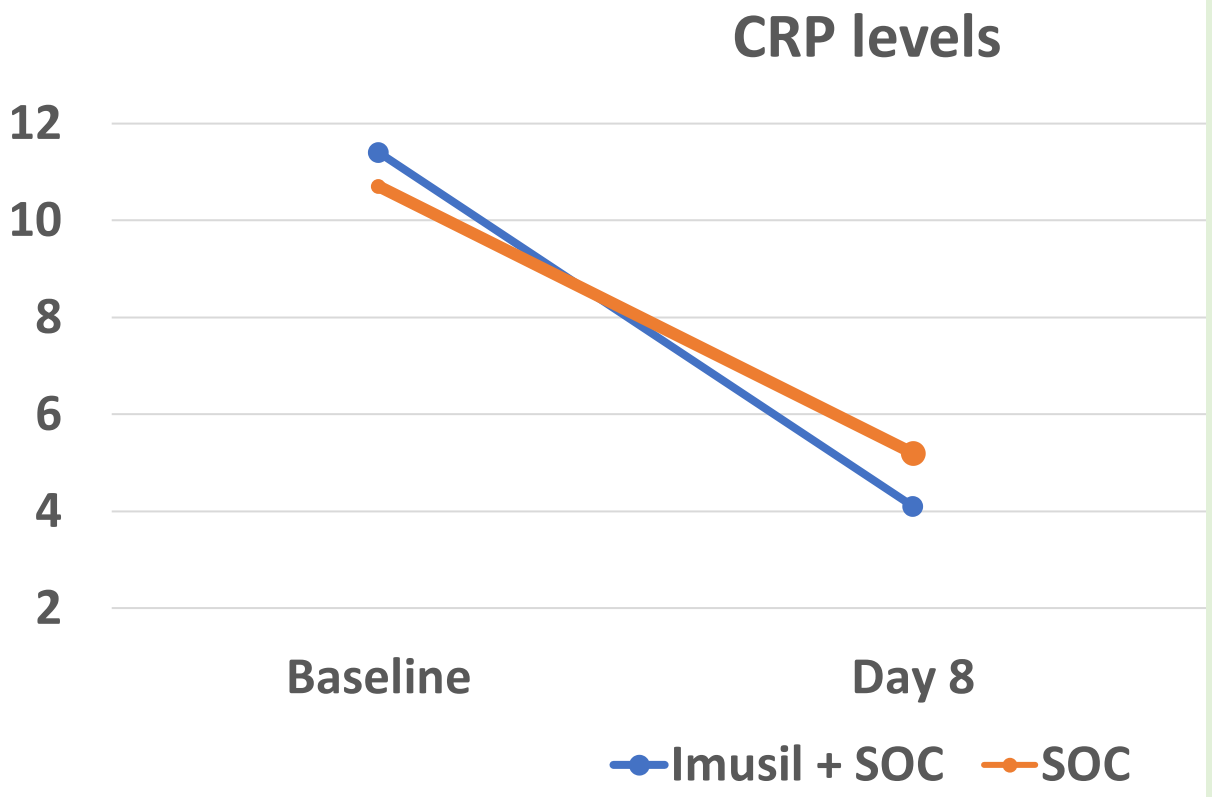
Results: Clinical Improvement

Imusil- 100%

SOC- 94%

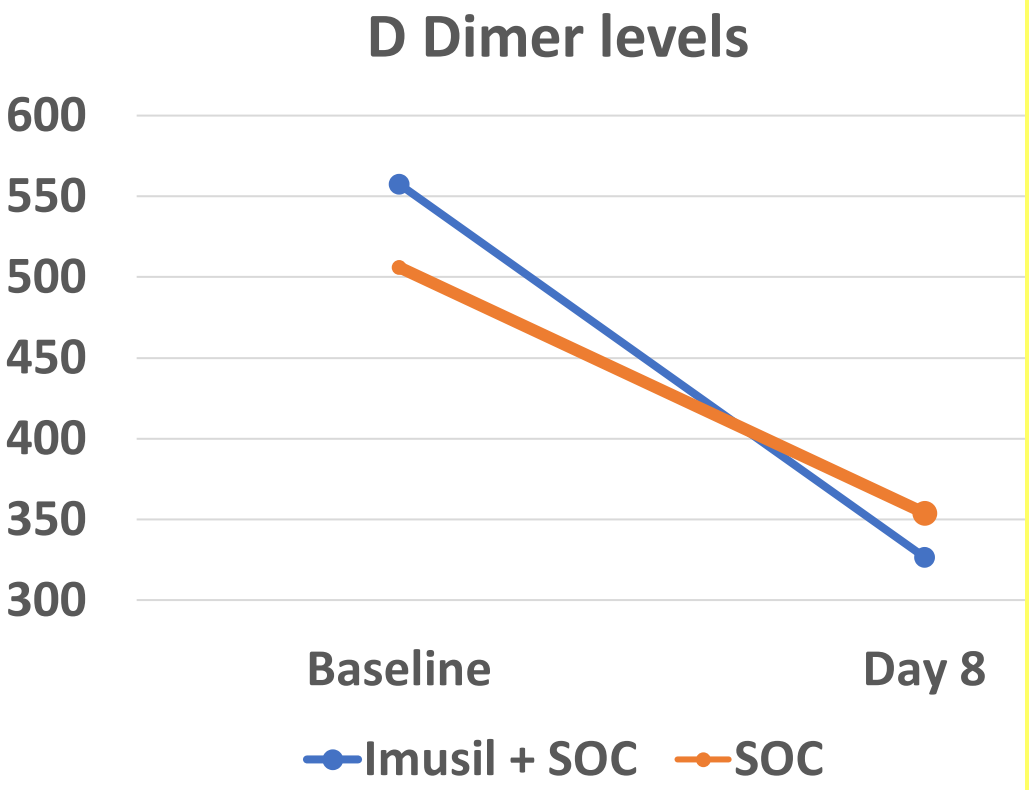
- **The proportion of subjects with a 2-point decrease in the "WHO Ordinal Scale" (Clinical Improvement) was 100% at end of study (EOS) in the Imusil®+SOC treatment arm.**
- **In the SOC treatment arm, 94% of subjects had a 2-point decrease in the "WHO Ordinal Scale" (Clinical Improvement) by end of study. There were 3 (6%) subjects in the SOC treatment arm who did not show a 2-point decrease in the "WHO Ordinal Scale" (Clinical Improvement).**
- **Numerically there were a higher number of subjects in the Imusil®+SOC treatment arm who had a 2-point decrease in the "WHO Ordinal Scale" (Clinical Improvement).**

Change in CRP



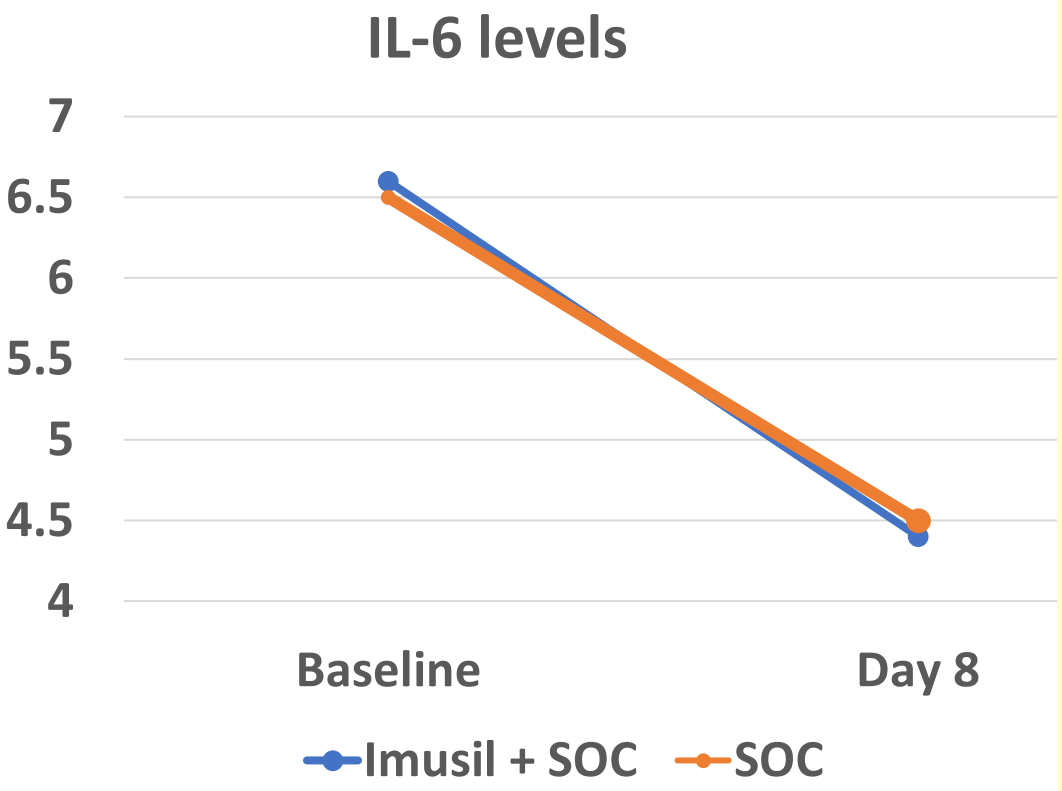
- In the Imusil®+SOC treatment group, the mean CRP at baseline was 11.4 ±13.41 mg/L, and on day 8 mean CRP was 4.1± 3.85 mg/L. At the end of day 8, the mean CRP declined in subjects who received Imusil®+SOC, and the mean difference observed was -7.34 mg/L.
- In the SOC treatment group, the mean CRP at baseline was 10.7 ± 11.53 mg/L, and on day 8, the mean CRP was 5.2±5.65 mg/L. At the end of day 8, the mean CRP declined in subjects who received SOC, and the mean difference observed was -5.50mg/L.
- The changes observed in CRP level in the Imusil®+SOC group were numerically higher than in the SOC group.

Change in D Dimer



- In Imusil®+SOC treatment group, mean D-Dimer at baseline was 557.5±235.38 ng FEU/mL, and on day 8 mean D-Dimer was 326.5 ± 114.53 ng FEU/mL. At the end of day 8, the mean D-Dimer level declined in subjects who received Imusil®+SOC, and the mean difference observed was -230.99 ng FEU/mL.
- In SOC treatment group, mean D-Dimer at baseline was 506.0 ± 175.44 ng FEU/mL, and on day 8 mean D-Dimer was 354.5±133.75 ng FEU/mL. At the end of day 8 the mean D-Dimer declined in subjects who received SOC, and the mean difference observed was -151.56 ng FEU/mL.
- The changes observed in D-Dimer level in Imusil®+SOC group were numerically higher than the SOC group.

Change in IL-6



- In Imusil®+SOC treatment group, mean IL-6 at baseline was 6.6±3.12 pg/mL, and on day 8+2 mean IL-6 was 4.4± 1.77 pg/mL. At the end of day 8+2, the mean IL-6 declined in subjects who received Imusil®+SOC, and the mean difference observed was -2.25 pg/mL.
- In SOC treatment group, mean IL-6 at baseline was 6.5 ± 2.68 pg/mL, and on day 8+2 mean IL-6 was 4.5±1.92 pg/mL. At the end of day 8+2 the mean IL-6 declined in subjects who received SOC, and the mean difference observed was -1.97 pg/mL.
- The changes observed in IL-6 level in Imusil®+SOC group were numerically higher than the SOC group.

Safety Conclusion

- **Overall, the drug was well tolerated in both treatment groups.**
- **There were no AEs reported in the Imusil®+SOC arm, and 2 (4.0%) subjects in the SOC arm reported adverse events (AE) in the study. Adverse events reported in the SOC treatment group were vomiting and pruritus during the study.**
- **There were no serious adverse events reported in the study.**
- **All the adverse events were reported as mild in intensity.**

Benefits of Imusil

01

RTPCR negativity is faster and quicker

02

Better control of Symptoms

03

Better reduction of CRP, IL-6, D-Dimer

04

Safe and well tolerated