**To:** [redacted]@cbg-meb.nl]
**From:** [redacted].
**Sent:** Tue 12/1/2020 12:34:40 PM
**Subject:** FW: Resultaten EMPACTA studie met tocilizumab
**Received:** Tue 12/1/2020 12:34:40 PM
FINAL EMPACTA unblinding media release_180920.pdf

Hoi [redacted]

Hierbij de laatste info die wij hebben * .
Volgens mij geldt deze zin nog steeds: Roche heeft op dit moment nog geen beslissing genomen over het indienen van deze studieresultaten tbv bijvoorbeeld een indicatie-uitbreiding.

Grt [redacted]

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**Van:** [redacted].
**Verzonden:** dinsdag 13 oktober 2020 09:24
**Aan:** [redacted]. <[redacted]@cbg-meb.nl>; [redacted] <[redacted]@cbg-meb.nl>; [redacted].
<[redacted]@cbg-meb.nl>
**Onderwerp:** FW: Resultaten EMPACTA studie met tocilizumab

Voila, toculizumab. Doorsturen naar [redacted]

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**Van:** [redacted]. <[redacted]@cbg-meb.nl>
**Verzonden:** vrijdag 25 september 2020 14:41
**Aan:** [redacted]. <[redacted]@cbg-meb.nl>
**Onderwerp:** FW: Resultaten EMPACTA studie met tocilizumab

Hoi [redacted]

Misschien heb je deze info al via een andere route gekregen, anders bij deze:
De studie met Roactemra in COVID patiënten heeft het primaire eindpunt gehaald: progression to mechanical ventilation or death by day 28.
Er is echter geen statistisch verschil in de mortality rate; blijkbaar doet het vooral wat op de longfunctie.

Roche heeft op dit moment nog geen beslissing genomen over het indienen van deze studieresultaten tbv bijvoorbeeld een indicatie-uitbreiding.

Groet
[redacted]

**Van:** [redacted] <[redacted]@roche.com>
**Verzonden:** vrijdag 25 september 2020 14:27
**Aan:** [redacted]. <[redacted]@cbg-meb.nl>
**CC:** Case <[redacted]@cbg-meb.nl>; [redacted] <[redacted]@roche.com>; [redacted] <[redacted]@roche.com>
**Onderwerp:** Resultaten EMPACTA studie met tocilizumab

Geachte mevrouw [redacted]

Wij willen het CBG graag informeren over de resultaten van studie EMPACTA met tocilizumab aangezien u in april 2020 contact heeft gehad met Roche inzake RoActemra en covid19 pandemie.
De resultaten van de studie zijn eerder deze week door ons hoofdkantoor opgestuurd naar de EMA. .

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**Outcome of Roche EMPACTA study: RoActemra in the treatment of severe COVID-19 pneumonia**

Dear MEB,
Please be informed that primary analysis results from the following Roche-sponsored Phase III trial are now available:
**Title:** A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Tocilizumab in Hospitalized Patients with COVID-19 Pneumonia

This study is evaluating the efficacy and safety of tocilizumab compared with a placebo in combination with standard of care therapy in hospitalized patients with COVID-19 pneumonia to prevent patients from progressing to require mechanical ventilation and/or death. Patients (388 evaluable) were enrolled from the US, Mexico, Kenya, South Africa, Peru, and Brazil. EMPACTA enrolled a predominantly minority patient population (87%).

The day 28 primary analysis shows that **the primary endpoint was met**. Patients with COVID-19 associated pneumonia who received RoActemra plus standard of care were 44% less likely to progress to mechanical ventilation or death compared to patients who received placebo plus standard of care (log-rank p-value = 0.0348; HR [95% CI] = 0.56 [0.32, 0.97]). The cumulative proportion of patients who progressed to mechanical ventilation or death by day 28 was 12.2% in the RoActemra arm versus 19.3% in the placebo arm.

Key secondary endpoints

- The difference in time to hospital discharge or "ready for discharge" to day 28 was not significant (median (days): RoActemra = 6; placebo (PBO) = 7.5; log-rank p-value = 0.2456; HR [95% CI] = 1.16 [0.90, 1.48]).
- The difference in time to improvement in ordinal clinical status to day 28 was not significant (median (days): RoActemra = 6; PBO = 7; log-rank p-value = 0.2597; HR [95% CI] = 1.15 [0.90, 1.47]).
- Time to clinical failure to day 28 was longer in the RoActemra arm compared to the placebo arm (median (days): RoActemra = not-estimable (NE); PBO = NE; log-rank p = 0.0217; HR [95% CI] = 0.55 [0.33, 0.92]). However, the difference cannot be considered statistically significant as other key secondary endpoints were not met.
- There was no statistical difference in mortality between patients who received RoActemra or placebo by day 28 (RoActemra = 10.4%; PBO = 8.6%, p-value = 0.5146, Difference [95% CI]: 2.0% [-5.2%, 7.8%]).

At day 28, incidence of infections was 10% and 11% in the RoActemra and placebo arms, respectively, and the incidence of serious infections was 5.0% and 6.3% in the RoActemra and placebo arms, respectively. The most common adverse events in patients who received RoActemra were constipation (5.6%), anxiety (5.2%), and headache (3.2%). The EMPACTA study did not identify any new safety signals for RoActemra.

At this time, Roche continues to analyze the results and there is no decision at this time on whether these data may be used to support a future filing.

A copy of the Press Release, disseminated on 18 September 2020, is attached for your information.

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Voor vragen kunt u contact met mij opnemen.
Met vriendelijke groet,

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**Roche Nederland B.V.**

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