To: [redacted]@takeda.com]
Cc: [redacted]; [redacted]@takeda.com]; [redacted]@sanquin.nl[[redacted]@sanquin.nl] [redacted]
[redacted]@sanquin.nl]; [redacted]@minvws.nl]; [redacted]@minvws.nl]; [redacted]
[redacted]@minvws.nl]; [redacted]@minvws.nl] [redacted]
[redacted]@minvws.nl]; [redacted]@minvws.nl]; [redacted]@minvws.nl]; [redacted]
([redacted])[[redacted]@minvws.nl]; [redacted]@minvws.nl] [redacted]@minvws.nl]
From: [redacted])
Sent: Fri 4/16/2021 8:08:19 AM
Subject: RE: Availability and allocation of investigational plasma-derivedtherapy against COVID-19
Received: Fri 4/16/2021 8:08:20 AM

Dear Mr. [redacted]

Thank you for the information on the ITAC trial outcomes.

We understand that the Alliance companies will not pursue authorization based on the trial results. In case there is any update on the product in the future, we would like to remain informed.

Kind regards,

[redacted]

[redacted]

Department of Pharmaceuticals and Medical Technology
Ministry of Health, Welfare and Sport
Parnassusplein 5 | 2511 VX | The Hague | The Netherlands
PO Box 20350 | 2500 EJ | The Hague | The Netherlands

P. 06 [redacted]
E. [redacted]@minvws.nl / [redacted]@minvws.nl

Van: [redacted] <[redacted]@takeda.com>
Verzonden: dinsdag 6 april 2021 14:04
Aan: [redacted]) <[redacted]@minvws.nl>
CC: [redacted] <[redacted]@takeda.com>; [redacted]@sanquin.nl; [redacted]; [redacted]@sanquin.nl>; [redacted].
([redacted]) <[redacted]@minvws.nl>; [redacted]) <[redacted]@minvws.nl>; [redacted])
<[redacted]@minvws.nl>; [redacted]) <[redacted]@minvws.nl> [redacted]
<[redacted]@minvws.nl>; [redacted]) <[redacted]@minvws.nl>; [redacted])
<[redacted]@minvws.nl>; [redacted]) <[redacted]@minvws.nl>; [redacted]) <[redacted]@minvws.nl>
Onderwerp: Availability and allocation of investigational plasma-derived therapy against COVID-19

Dear Ms. [redacted]

As follow up to our recent communications regarding the CoVIg-19 Plasma Alliance, we would like to advise that the ITAC trial, which studied whether an investigational anti-coronavirus hyperimmune intravenous immunoglobulin (H-Ig) could reduce the risk of disease progression when added to standard of care treatment in hospitalized adult patients, did not meet its endpoints. Please see the attached press release for more information.

Based on the results, we do not anticipate that Alliance companies will pursue authorization of a Covid-19 hyperimmune therapy, subject of course to each individual company's independent decision.

While we are disappointed in the outcome of the trial, we are proud that we undertook this work and hope that this research can add to understanding of this challenging virus with the possibility to inform new strategies for patient care. We are grateful to government and other public health agencies, as well as patients and healthcare professionals around the world, who supported the Alliance.

Thank you, and please let us know if there is anything further you would like from us on this topic.

Kind regards,

5.1.2e

From: 5.1.2e
Sent: 19 March 2021 14:38
To: 5.1.2e) < 5.1.2e @minvws.nl>
Cc: 5.1.2e < 5.1.2e @takeda.com>; 5.1.2e @sanquin.nl 5.1.2e < 5.1.2e @sanquin.nl>; 5.1.2e 5.1.2e
(5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e)
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< 5.1.2e @minvws.nl>; 5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e) < 5.1.2e @minvws.nl>
Subject: RE: Availability and allocation of investigational plasma-derived therapy against COVID-19

Dear 5.1.2e

On behalf of the Alliance, thank you for expressing your interest in receiving human SARS-CoV-2 immunoglobulin therapy as a donation, assuming and following EU authorization.

The Alliance is currently finalizing the document with associated terms and conditions, which we refer to in our letter. We look forward to writing to you again in the coming days with more information.

Kind regards,

5.1.2e

From: 5.1.2e) < 5.1.2e @minvws.nl>
Sent: 12 March 2021 16:42
To: 5.1.2e 5.1.2e @takeda.com>
Cc: 5.1.2e 5.1.2e @takeda.com>; 5.1.2e @sanquin.n 5.1.2e 5.1.2e @sanquin.nl>; 5.1.2e 5.1.2e
(5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e)
< 5.1.2e @minvws.nl>; 5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e
< 5.1.2e @minvws.nl>; 5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e)
< 5.1.2e @minvws.nl>; 5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e) < 5.1.2e @minvws.nl>
Subject: RE: Availability and allocation of investigational plasma-derived therapy against COVID-19

Be advised that this email came from outside Takeda / お知らせ：社外から送信されたメールです

Dear 5.1.2e

Thank you for the offered opportunity to show interest in a donation of your investigational plasma-derived therapy against COVID-19.

The Netherlands would like to express interest in the donation. However, we do want to stress that the Netherlands already acquired a modest amount of the Nanogam product from Sanquin. We therefore want to show solidarity to countries that do not have access to any form of a plasma-derived therapy against COVID-19 and we would fully understand if you would take this into consideration in your allocation algorithm.

Please feel free to send the confirmation document with associated terms and conditions as suggested. My colleagues 5.1.2e 5.1.2e 5.1.2e , 5.1.2e , 5.1.2e and myself are in the lead for this. Could you please share the additional information with this group (all copied in this email)?

Best wishes,

5.1.2e

Department of Pharmaceuticals and Medical Technology
Ministry of Health, Welfare and Sport
Parnassusplein 5 | 2511 VX | The Hague | The Netherlands
PO Box 20350 | 2500 EJ | The Hague | The Netherlands

P. 06 5.1.2e
E. 5.1.2e @minvws.nl / 5.1.2e @minvws.nl

Van: Corliss, Richard < 5.1.2e @takeda.com>
Verzonden: maandag 8 maart 2021 10:10
Aan: 5.1.2 5.1.2e) < 5.1.2e @minvws.nl>; 5.1.2e @minvws.nl; 5.1.2e)
< 5.1.2e @minvws.nl> 5.1.2h < 5.1.2e @minvws.nl>; 5.1.2e)
< 5.1.2e @minvws.nl>
CC: 5.1.2e < 5.1.2e @takeda.com>; 5.1.2e < 5.1.2e @sanquin.nl> 5.1.2e < 5.1.2e @sanquin.nl>
Onderwerp: Availability and allocation of investigational plasma-derived therapy against COVID-19

To the Ministers of Health in the Member States of the European Union and Switzerland

Regarding: Availability and allocation of investigational plasma-derived therapy against COVID-19

Dear Minister,

I am writing to you on behalf of the CoVIg-19 Plasma Alliance.

The purpose of this communication is to provide you with an update on our program to develop a **plasma-derived human SARS-CoV-2 Hyperimmune globulin (H-Ig) therapy** as a potential treatment for patients hospitalized with COVID-19, and to be advised of your interest in receiving a quantity of this therapy should it receive authorization in the EU, and as supplies may allow.

As we continue to learn how COVID-19 manifests, a variety of preventative and therapeutic approaches will be needed to treat individuals at different stages of disease. The SARS-CoV-2 investigational H-Ig medicine has been developed with the **potential to treat individuals who have been hospitalized with the infection** but are still in the early stages of the disease.

To expedite development, the **CoVIg-19 Plasma Alliance**, founded by CSL Behring and Takeda in April 2020, and including Biopharma, Biotest, GC Pharma, LFB, NBI, Octapharma and Sanquin, **collaborated with the National Institute of Allergy and Infectious Diseases (NIAID) of the U.S. National Institutes of Health (NIH) on an innovative multi-national Phase 3 pivotal clinical trial.** The ITAC clinical study is expected to complete by mid-March, having enrolled more than 500 patients globally. If data (expected in early April 2021) are positive, several Alliance member companies will pursue regulatory submissions to be able to make this therapeutic option available to patients as quickly as possible.

In the interest of public and patient health, **Alliance member companies have collaborated to develop and produce the H-Ig at their own expense and have committed to donate product produced on behalf of the Alliance**, if regulatory authorization is granted. They also have the option to continue to manufacture and share the information to do so with other plasma fractionators around the world if patient need remains high.

As with all plasma-derived therapies, how much H-Ig the Alliance can produce depends on the convalescent plasma donations actually received. Given this reliance on donations, to date we have been able to produce quantities of product in the range of thousands of doses versus the typically much larger scale you might expect for vaccines and products created with recombinant or synthetic materials. At this time, we anticipate up to **several thousand doses in total can be made available across the EU region once authorized.** Additional supply for future distribution is under preparation and dependent on regulatory outcomes and dynamics of the disease and vaccination efforts around the world.

The Alliance has developed prospectively a **shared algorithm to ensure equitable allocation of available product and to best meet greatest patient need**. This dynamic model prioritizes countries where regulatory authorization is expected based on real time data (sourced from the WHO database) indicating the **severity** (number of deaths daily) and **progression** (change in weekly cases) of the pandemic. It also provides incremental allowance for those countries that have contributed convalescent plasma. The Alliance will

run the allocation model and confirm potential volume for your particular country around the time we plan to submit for EU authorization.

If you would like your country to be considered to receive human SARS-CoV-2 immunoglobulin therapy as a donation (assuming and following EU authorization), **I kindly request that you indicate this by 15th March via email to [5.1.2e @takeda.com].** I will then send you a document to confirm your interest in receiving a donation with associated terms and conditions. Importantly, we will require you to specify a location and named recipient with whom to organize delivery of a potential donation as early as possible. **Please be advised, that only those countries that respond expressing interest in receiving the SARS-Cov-2 immunoglobulin therapy will be included in the allocation calculation that will determine product distribution upon authorization.**

If you would like to discuss further, I will be glad to refer you to a team within our company who can answer your questions and provide further details on behalf of the Alliance.

Yours sincerely,

5.1.2e

5.1.2e

Takeda

Better Health, Brighter Future

5.1.2e

Takeda

5.1.2e @takeda.com