Zorginstituut Nederland

> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport
PO Box 20350
2500 EJ THE HAGUE

National Health Care Institute
Care
Medicinal Products

Willem Dudokhof 1
1112 ZA Diemen
PO Box 320
1110 AH Diemen
www.zorginstituutnederland.nl
info@zinl.nl

T +31 (0)20 797 85 55

2023000582

Date 1 March 2023
Re: Progress report conditional inclusion procedure for orphan drugs, conditionals and exceptionals

Our reference
2023000582

Dear Mr Kuipers,

Please find enclosed the *2022 Progress Report for the conditional inclusion of orphan drugs, conditionals and exceptionals*.

With the conditional inclusion procedure (CI) for orphan drugs, conditionals and exceptionals, the National Health Care Institute is committed to proactive package management to promote appropriate care. With this procedure, patients with a severe disorder and an unmet treatment need could, under conditions, be eligible for reimbursement of promising medicines that, due to insufficient evidence, do not yet meet the established medical science and medical practice. After sufficient evidence has been gathered for the test on the established medical science and medical practice, the medicinal product is either definitively included in or excluded from the basic health care package.

Once a year, a meeting is organised for each CI process to discuss the progress and relevant interim findings of the CI process. Based on this annual monitoring point, the National Health Care Institute assesses progress based on patient inclusion and feasibility of the research process among other things. The National Health Care Institute then writes a progress report, in which it will also advise on any adjustment or termination of the CIprocesses.

The CI process has been in force since October 2019. Since October and November 2021, the first three CI processes were initiated for four medicinal products. Since all these processes have now been running for at least one year, the National Health Care Institute will be releasing the first progress report.

The National Health Care Institute advises to continue all 3 CI processes. It is expected that in 2023, the National Health Care Institute will assess whether entrectinib (Rozlytrek®) and larotrectinib (Vitrakvi®) meet the established medical science and medical practice. The CI process for these medicinal products may then be completed prematurely. The CI process for rhPTH 1-84 (Natpar®) will end prematurely this year, as treating physicians are using 2023 to switch their patients to an alternative due to the impending production stop. We informed you about this on 2 November 2022 (our reference: 202204285). The CI

process for ataluren (Translarna®) is expected to end on 1 February 2024. This means that the National Health Care Institute will start to assess whether the medicinal product meets the established medical science and medical practice in 2023.

Since the National Health Care Institute is holding exploratory conversations with parties about several medicinal products, the institute expects to present you with several potential candidates and to start several CI processes in the coming year. In addition, the National Health Care Institute wants to draw more attention internationally to this proactive form of package management. The National Health Care Institute will therefore invest in the exchange of experiences with other European countries in the near future, thus ensuring that patients with a serious disease and an unmet medical need can be considered for a treatment with a promising medicinal product.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

National Health Care Institute
Care
Medicinal Products

Date
1 March 2023

Our reference
2023000582