Briefing Book

For Scientific Advice at Canada’s Drug Agency

[Month, Day, Year]

CONFIDENTIAL

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# Tables and Figures

# Annexes

# Abbreviations

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# 1. Rationale for Seeking Advice

 [Response]

#

# 2. Name or Code Name Product

[Response]

#

# 3. Background Information

## 3.1 Overview of the Disease

[Response]

## 3.2 Treatment Options and Relevant Guidelines

[Response]

## 3.3 Current Unmet Need

[Response]

## 3.4 Regulatory Scientific Advice *(Provide date in format Month, Day, Year.)*

|  |  |  |
| --- | --- | --- |
| Agency | Date/Expected Date | Minutes Attached (Y/N) |
| Health Canada |  |  |
| FDA |  |  |
| EMA |  |  |

FDA = Food and Drug Administration (US); EMA = European Medicines Agency; Y/N = yes/no.

## 3.5 Health Technology Assessment Scientific Advice/Early Dialogues *(Provide date in format Month, Day, Year.)*

|  |  |
| --- | --- |
| Country/Agency | Date/Expected Date |
|  |  |
|  |  |
|  |  |

# 4. Data Currently Available on the Product

## 4.1 Mode of Action or Pharmacological Class

[Response]

## 4.2 Proposed Dosing Regimen and Route Administration

[Response]

## 4.3 Indication and Target Population

[Response]

## 4.4 Regulatory Status

(*When is marketing authorization expected? Does the product have marketing authorization in other indications? Please provide date or expected date in format Month, Day, Year, or indicate N/A for not applicable. You may add additional rows to this table for more indications, as needed. Delete rows if they are not required.*)

|  |  |  |  |
| --- | --- | --- | --- |
| Indication | Health Canada | EMA | FDA |
| [Intended indication] |  |  |  |
| [Other indication #1] |  |  |  |
| [Other indication #2] |  |  |  |

FDA = Food and Drug Administration (US); EMA = European Medicines Agency.

## 4.5 Summary of Patient Engagement (If Available)

[Response]

## 4.6 Clinical Data Available to Date

(Insert relevant subsections, as required.)

[Response]

# 5. Product Value Proposition

[Response]

# 6. Proposed Clinical Development Program

(Insert relevant subsections, as required. May include RWE evidence generation plans.)

[Response]

# 7. Proposed Economic Analysis

*(If appropriate, your response may indicate that background on the proposed economic analysis is not provided, as economic questions have not been included in the* Briefing Book*.)*

[Response]

# 8. Questions and Applicant’s Position

## 8.1 Questions on the Proposed Clinical Development Plan

### Question 1:

[Applicant’s position]

*(Please note that questions posed should be as specific as possible, with a detailed rationale for the approach proposed.)*

### Question 2:

[Applicant’s position]

*(Insert additional questions here.)*

## 8.2 Questions on the Proposed Economic Evaluation Plan

### Question 3:

[Applicant’s position]

### Question 4:

[Applicant’s position]

*(Insert additional questions here.)*

# References

1. abc
2. abc