Canada's Drug Agency
L'Agence des médicaments du Canada
Drugs. Health Technologies and Systems. Médicaments, technologies de la santé et systèmes.

**Proposed Project Scope**

# Pertuzumab in combination with trastuzumab and chemotherapy for the neoadjuvant treatment of early stage HER2-positive breast cancer

Date: January 2025

## Background and Rationale

CDA-AMC received a request from public drug programs for a Non-Sponsored Reimbursement Review of pertuzumab in combination with trastuzumab and chemotherapy for neoadjuvant treatment of early stage HER2-positive breast cancer

### Table I: Policy Questions

| Item | Policy Question |
|---|---|
| 1 | Should pertuzumab in combination with trastuzumab and chemotherapy for neoadjuvant treatment of early stage HER2-positive breast cancer be reimbursed? |

### Table II: Products Available in Canada

| Product | Manufacturer |
|---|---|
| Pertuzumab and trastuzumab | Hoffmann-La Roche |
| | |

# Project Description

### Table III: Project Scope

| Criteria | Description |
|---|---|
| **Population** | Patients with early stage HER2-positive breast cancer |
| **Intervention(s)** | Neoadjuvant pertuzumab (4-6 cycles) and trastuzumab with chemotherapy, followed by adjuvant trastuzumab or T-DM1 for up to 1 year |
| **Comparators** | Neoadjuvant trastuzumab with chemotherapy, followed by adjuvant trastuzumab or T-DM1 for up to 1 year |
| **Outcomes** | Complete pathologic response<br>Safety/Toxicity of the entire treatment strategy (e.g., including the adjuvant portion of the treatment plan (e.g., trastuzumab or TDM-1)<br>Event-free survival<br>Disease-free survival<br>Overall survival |

### Table IV: Research Questions

| Item | Questions |
|---|---|
| 1 | What is the effectiveness of pertuzumab in combination with trastuzumab and chemotherapy for neoadjuvant treatment of early stage HER2-positive breast cancer? |
| 2 | What are the benefits of reduced toxicity as there is published evidence that the addition of neoadjuvant pertuzumab allows omission of anthracycline? |
| 3 | What are the benefits of the reduction of toxicity related to lower use of adjuvant T-DM1? |
| 4 | What is the expected cost comparison of the different neoadjuvant and adjuvant treatment strategies? (e.g., if neoadjuvant pertuzumab-trastuzumab-chemotherapy leads to higher pathologic complete response, fewer patients will receive adjuvant T-DM1). |

## Key Project and Protocol Components

This project will follow the Procedures for Non-Sponsored Reimbursement Reviews.

## Status of the Document

This proposed project scope is being posted for information.