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Project Details	
Client: Pharma-Y	Product: BRAND-X
Project: HCP Onboarding Kit	Brief Timeline
[blue text]: Paragraph styles or design notes [red text]: Reference paths [pink text]: Variable copy [green text]: Links or functionality notes	

Change Log	
Date: 13-16 Oct 20XX	V0.0: Initial copy development (TS)
18 Oct 20XX	V0.1: Med Reg edits (TS)

0.0 HOME
[PAGE 1 – FRONT COVER]

[Logos]
< PrBRAND-X ™>
< ™Pharma-Y>

[Call out]
Now approved

[Headline]
Introducing BRAND-X, a ready-to-use AAAA-directed bispecific immunotherapy[1]

[Subhead]
With biweekly dosing after 24 weeks in responding patients* [BRAND-X PM/ p.5 B

[Indication]
BRAND-X (Loremipsum solution for injection), indicated for the treatment of adult patients with relapsed or refractory Disease-Z who have received at least 3 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD#8 monoclonal antibody, and who have demonstrated disease progression on the last therapy, has been issued market authorization with conditions, pending the results of trials to verify its clinical benefit. Patients should be advised of the nature of the authorization.
For further information on BRAND-X, please refer to Health Canada's Notice of Compliance with Conditions - drug products website: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/notice-compliance/conditions.html. [BRAND-X PM/ / p.1 A]

[Abbreviation]
AAAA=Lorem ipsum dolor sit amet.

[Footnote]
* For patients who have received at least 24 weeks of treatment and have achieved a response (i.e., a partial response or better that has been maintained for at least 2 months), the dose frequency can be reduced to every other week from Week 25. [BRAND-X PM/ p.5 A]

1.0 TABLE OF CONTENTS

[PAGE 2 – WELCOME TO THE ONBOARDING KIT]

[Headline]

Table of contents

[Copy]

2.0 INTRODUCING BRAND-X
[PAGE 3]

[Copy]
BRAND-X is a AAAA- and CD#- directed bi-specific antibody indicated as monotherapy designed to:[1] [BRAND-X PM/ p.4 D]

- Selectively target and activate T cells re-directed against AAAA-expressing malignant plasma cells [BRAND-X PM/ p.23 B]
- Activated T-cells cause proinflammatory cytokine release and result in cell lysis [BRAND-X PM/ p.23 C]

BRAND-X offers the convenience of:[1]

- Biweekly dosing after 24 weeks in responding patients* [BRAND-X PM/ p.5 A]
- Subcutaneous administration by a healthcare provider [BRAND-X PM/ p.13 A]
- Ready-to-use availability [BRAND-X PM/ p.13 B]
- Single-dose vial [BRAND-X PM/ p.13 C]
- Fixed dose, with no weight-based calculations [BRAND-X PM/ p.5 C]

[Abbreviation]
AAAA= Lorem ipsum dolor sit amet.

[Footnote]
* For patients who have received at least 24 weeks of treatment and have achieved a response (i.e., a partial response or better that has been maintained for at least 2 months), the dose frequency can be reduced from every week to every other week from Week 25. [BRAND-X PM/ p.5 A]

3.0 STUDY DESIGN

[PAGE 4]

[Eyebrow/Tab]

TRIAL-X trial

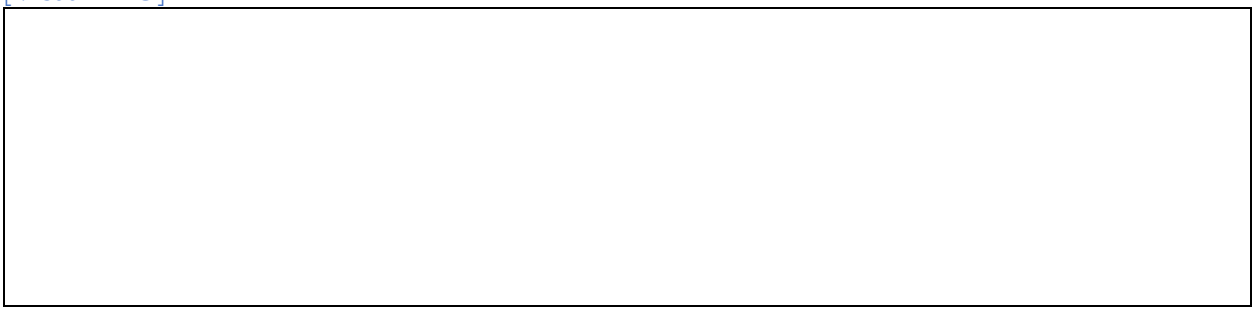
[Headline]

BRAND-X was studied in an open-label, non-randomized, multi-center, Phase 2 trial[1] [BRAND-X PM/ p.27 A]

[Subhead]

In adult patients with relapsed or refractory Disease-Z [BRAND-X PM/ p.27 A]

[Visual-FPO]



[Copy near graph]

Adapted from product monograph

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Trial-X cohort A inclusion criteria (N=123): [BRAND-X PM/ p.27 B]

- Refractory to ≥1 IMiD, ≥1 PI, and ≥1 anti-CD# mAb [BRAND-X PM/ p.27 F]
- AAAA-directed therapy-naïve [BRAND-X PM/ p.27 B]
- ECOG performance status ≤2 [BRAND-X PM/ p.27 C]
- Estimated CrCL≥30 mL/min [BRAND-X PM/ p.27 C]
- Platelet count ≥25 × 10^9/L [BRAND-X PM/ p.27 C]
- ANC ≥1.0 × 10^9/L [BRAND-X PM/ p.27 C]

Step-up doses

BRAND-X 12 mg SC on Day 1 and 32 mg SC on Day 4 (Week 1) [BRAND-X PM/ p.27 D]

Full dose

BRAND-X 76 mg SC QW from Day 8 (Week 2) through Week 24, then Q2W thereafter (28-day cycle)* [BRAND-X PM/ p.27 E]

Treatment until disease progression or unacceptable toxicity [BRAND-X PM/ placeholder]

[Copy]

Efficacy endpoints: [BRAND-X PM/ p.29 table 12]

- Objective response rate
- Complete response rate
- Duration of response

[Abbreviations]

ANC=absolute neutrophil count; AAAA= Lorem ipsum dolor sit amet; CrCL=creatinine clearance; ECOG=eastern cooperative oncology group; IMiD=immunomodulatory agent; IMWG=international myeloma working group; mAB=monoclonal antibody; PI=proteasome inhibitor; QW=once weekly; Q2W=once every 2 weeks; SC=subcutaneous.

[Footnote]

* After 24 weeks, in patients who achieved an IMWG response category of partial response or better with responses persisting for at least 2 months, the dose interval was changed from 76 mg every week to 76 mg every 2 weeks. [BRAND-X PM/ p.27 E]

4.0 EFFICACY
[PAGE 5]

[Eyebrow/Tab]
Baseline characteristics

[Copy]
Select baseline characteristics:[1]
• Median age 68 years: range 36 to 89 years with 9.5% of patients ≥75 years of age [BRAND-X PM/ p.28 A]
• Disease stage at study entry: 22.8% in Stage I, 55.3% in Stage II, and 15.4% in Stage III [BRAND-X PM/ p.28 E]
• Initial diagnosis to study enrollment median time: 72.9 (range: 16 to 228) months [BRAND-X PM/ p.28 F]
• Triple-class refractory patients: 97% [BRAND-X PM/ p.28 C]
• Median prior lines of therapy: 5.0 (range: 2 to 22) [BRAND-X PM/ p.28 B]
• Extramedullary disease*: 32% [BRAND-X PM/ p.28 D]

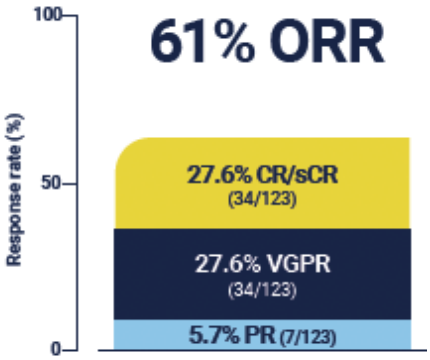
[Eyebrow/Tab]
Efficacy Data

[Headline]
Responses observed in Cohort A – Participants with no prior AAAA-directed treatment[1]

[Subhead]
84.4% probability of maintaining a response at 9 months† [BRAND-X PM/ p.29 C]

[Copy]
- 61% of patients achieved an objective response rate† [BRAND-X PM/ p.29 A]
- 27.6% of patients achieved a complete response rate†‡ [BRAND-X PM/ p.29 B]
- Median time to first response†: 1.2 months (range: 0.9 to 7.4; n=75) [BRAND-X PM/ p.29 D]
- Duration of response†: 84.4% probability of maintaining a response at 9 months (95% CI: 72.7–91.4) [BRAND-X PM/ p.29 C]

[Visual-FPO] [BRAND-X PM/ p.29 A, B]



[Copy for graph]
[y-axis label] Response rate (%)

[Copy near graph]
Adapted from product monograph

Art note: please keep the copy on the left and the visual on the right

[Abbreviations]
BICR=Blinded Independent Central Review; AAAA= Lorem ipsum dolor sit amet; CR=complete response; IMiD=immunomodulatory agent; IMWG=international myeloma working group; mAB=monoclonal antibody; ORR=objective response rate; PI=proteasome inhibitor; PR=partial response; sCR=stringent complete response; VGPR=very good partial response.

[Footnotes]
* Defined by BICR as the presence of any plasmacytoma (extramedullary and/or paramedullary) with a soft-tissue component. [BRAND-X PM/ p.28 D]

† Response rate and duration of response are assessed by BICR based on the IMWG criteria. [BRAND-X PM/ p.28 G]

‡ Defined as complete response plus stringent complete response. [BRAND-X PM/ p.29 B]

5.0 SAFETY PROFILE
[PAGE 6]

[Headline]
BRAND-X has a generally manageable safety profile[1]

[Copy]
Adverse reaction overview in Trial-X study patients:

- The most frequent adverse reactions of any grade were adverse reaction-x (57.9%), anaemia (53.6%), neutropenia (44.3%), fatigue (42.6%), diarrhea (35.5%), thrombocytopenia (35.0%), lymphopenia (29.5%), decreased appetite (26.2%), rash (25.7%), arthralgia (21.9%), nausea (21.3%), hypokalemia (21.3%), pyrexia (21.3%), injection site reaction (21.3%), and dry skin (20.8%) [BRAND-X PM/ p.19 B]
- Serious adverse reactions were reported in 68.3% of patients, including pneumonia (25.1%), sepsis (13.1%), adverse reaction-x (12.6%), anaemia (5.5%), upper respiratory tract infection (4.4%), urinary tract infection (3.3%), dyspnoea (2.2%), and febrile neutropenia (2.2%) [BRAND-X PM/ p.19 C]

[Table title]
Adverse reactions (≥10%) in patients who received BRAND-X in Trial-X

[Table] [BRAND-X PM/ p.19 A]

System Organ Class Preferred Term	BRAND-X n = 183	
	All Grades (%)	Grade 3/4 (%)
Blood and lymphatic system disorders		
Anemia*	53.6	42.1
Neutropenia†	44.3	42.6
Thrombocytopenia‡	35.0	25.1
Lymphopenia§	29.5	27.3
Leucopenia‖	15.8	10.9
Cardiac disorders		
Cardiac arrhythmia¶	16.4	1.6
Gastrointestinal disorders		
Diarrhea	35.5	1.1
Nausea	21.3	0
Constipation	14.2	0
Vomiting	14.2	0
General disorders and site administration conditions		
Fatigue#	42.6	5.5
Injection site reaction**	37.2	0
Pyrexia	21.3	2.7
Edema††	18.0	1.1

System Organ Class Preferred Term	BRAND-X n = 183	
	All Grades (%)	Grade 3/4 (%)
Immune system disorders		
Cytokine release syndrome	57.9	0.5
Hypogammaglobulinemia‡‡	13.1	2.2
Infections and infestations		
Upper respiratory tract infection§§	34.4	4.9
Pneumonia‖‖	31.7	19.1
Sepsis¶¶	15.3	10.9
Urinary tract infection##	12.0	4.4
Injury, poisoning and procedural complications		
Fall	10.4	0.5
Investigations		
Transaminases increased***	15.8	4.9
Metabolism and nutrition disorders		
Decreased appetite	26.2	1.1
Hypokalemia	21.3	8.2
Musculoskeletal and connective tissue disorders		
Arthralgia†††	21.9	1.1
Nervous system disorders		
Headache	18.0	0
Encephalopathy‡‡‡	14.2	2.2
Sensory neuropathy§§§	12.6	0.5
Motor dysfunction‖‖‖	14.2	1.1
Psychiatric disorders		
Insomnia	13.1	0
Respiratory, thoracic and mediastinal disorders		
Cough¶¶¶	24.0	0
Dyspnea###	15.8	3.8
Skin and Subcutaneous Tissue disorders		
Rash****	25.7	0
Dry skin	13.7	0
Skin exfoliation††††	10.4	0
Vascular disorders		
Hemorrhage‡‡‡‡	12.6	1.6

[Abbreviation]

CRS=cytokine release syndrome.

[Footnotes] [BRAND-X PM/ p.19 C]

* Anemia includes anaemia, haemoglobin decreased, red blood cell count decreased, haematocrit decreased, normochromic anaemia, normocytic anaemia, normochromic normocytic anaemia, aplasia pure red cell.
† Neutropenia includes neutropenia, neutrophil count decreased, neutrophil percentage decreased, cyclic neutropenia, agranulocytosis, granulocytopenia, granulocyte count decreased.
‡ Thrombocytopenia includes thrombocytopenia, platelet count decreased.
§ Lymphopenia includes lymphopenia, lymphocyte count decreased, lymphocyte percentage decreased, CD4 lymphocytes decreased, CD4 lymphocyte percentage decreased, CD8 lymphocytes decreased, CD8 lymphocyte percentage decreased.
‖ Leucopenia includes leucopenia, white blood cell count decreased.
¶ Cardiac arrhythmia includes atrial fibrillation, bradycardia, sinus bradycardia, sinus tachycardia, tachycardia, ventricular extrasystoles, ventricular tachycardia.
# Fatigue includes fatigue, asthenia, malaise.
** Injection site reaction includes injection site reaction, injection site erythema, injection site pruritus, injection site rash, injection site induration, injection site pain, injection site urticaria, injection site dryness, injection site haemorrhage, injection site inflammation.
†† Edema includes oedema, oedema peripheral, eye oedema, fluid retention, lip oedema, localised oedema, periorbital oedema, peripheral swelling.
‡‡ Hypogammaglobulinemia includes participants with adverse events of blood immunoglobulin G decreased, hypogammaglobulinaemia, immunoglobulins decreased.
§§ Upper respiratory tract infection includes upper respiratory tract infection, sinusitis, acute sinusitis, pharyngitis, rhinitis, rhinovirus infection, viral upper respiratory tract infection, bronchitis viral, chronic sinusitis, nasopharyngitis, sinusitis bacterial, bronchitis, respiratory tract infection viral.
‖‖ Pneumonia includes pneumonia, COVID-19 pneumonia, bronchopulmonary aspergillosis, lower respiratory tract infection, lower respiratory tract infection viral, pneumocystis jirovecii pneumonia, pneumonia adenoviral, pneumonia bacterial, pneumonia cytomegaloviral, pneumonia fungal, pneumonia influenzal, pneumonia pseudomonal, pneumonia viral.
¶¶ Sepsis includes sepsis, bacteraemia, device related bacteraemia, device related sepsis, escherichia bacteraemia, escherichia sepsis, klebsiella sepsis, pseudomonal sepsis, septic shock, staphylococcal bacteraemia, staphylococcal sepsis, streptococcal sepsis, urosepsis.
Urinary tract infection includes urinary tract infection, cystitis, urinary tract infection bacterial, escherichia urinary tract infection, urinary tract infection enterococcal.
*** Transaminases increased includes alanine aminotransferase increased and aspartate aminotransferase increased.
††† Arthralgia includes arthralgia, pain in extremity.
‡‡‡ Encephalopathy includes agitation, altered state of consciousness, cognitive disorder, confusional state, delirium, depressed level of consciousness, disorientation, hallucination, lethargy, memory impairment, metabolic encephalopathy, somnolence, toxic encephalopathy.
§§§ Sensory neuropathy includes burning sensation, dysesthesia, hypoesthesia, neuropathy peripheral, paresthesia, parosmia, peripheral sensorimotor neuropathy, peripheral sensory neuropathy, polyneuropathy, sensory loss.
‖‖‖ Motor dysfunction includes ataxia, balance disorder, gait disturbance, motor dysfunction, muscle contracture, muscle spasms, muscular weakness, peripheral motor neuropathy, peroneal nerve palsy, tremor.

¶¶¶ Cough includes cough, productive cough, upper-airway cough syndrome.
Dyspnea includes dyspnea, dyspnea exertional, respiratory distress.
**** Rash incudes erythema, palmar-plantar erythrodysaesthesia syndrome, rash, rash erythematous, rash macular, rash maculo-papular, rash pustular, symmetrical drug-related intertriginous and flexural exanthema.
†††† Skin exfoliation includes dermatitis exfoliative, dermatitis exfoliative generalised, skin exfoliation.
‡‡‡‡ Hemorrhage includes anal haemorrhage, conjunctival haemorrhage, diarrhoea haemorrhagic, ear haemorrhage, epistaxis, haemarthrosis, haematoma, haematoma muscle, haematuria, haemorrhoidal haemorrhage, intestinal haemorrhage, rectal haemorrhage, subdural haematoma, upper gastrointestinal haemorrhage, vascular access site haemorrhage.

5.0 SAFETY PROFILE
[PAGE 7]

[Headline]
Laboratory abnormalities in TRIAL-X study patients[1]

[Table title]
Select laboratory abnormalities (≥30%) that worsened from baseline in cohort A and B patients [BRAND-X PM/ p.22 A]

[Table] [BRAND-X PM/ p.22 A]

Laboratory Abnormality	**BRAND-X n = 183**	
	All Grades (%)	Grade 3/4 (%)
Hematology		
Hemoglobin decreased	68.1	43.4
Lymphocyte count decreased	90.7	83.6
Neutrophil count decreased	61.7	50.8
Platelet count decreased	61.2	31.7
White blood cell decreased	68.9	40.4
Chemistry		
Albumin decreased	55.2	5.5
Alkaline phosphatase increased	34.4	1.1
ALT increase	35.5	3.8
AST increase	39.8	5.5
Creatinine clearance decreased	32.2	9.9
Creatinine increased	37.9	3.3
Potassium decrease	36.3	8.2

[Abbreviations]
ALT=alanine transaminase; AST=aspartate transaminase.

6.0 MANAGING ADVERSE REACTIONS
[PAGE 8]

[Headline]
Management of adverse reaction-x in patients treated with BRAND-X[1]

[Copy]
CRS in BRAND-X -treated patients:

- BRAND-X can cause life-threatening or fatal adverse reaction-x reactions [BRAND-X PM/ p.16 C]
- Grade 1 adverse reaction-x occurred in 43.7% of patients, Grade 2 in 13.7%, and Grade 3 in 0.5%. Recurrent adverse reaction-x occurred in 13.1% of patients [BRAND-X PM/ p.16 D]
- CRS occurred after step-up dose 1 in 43.2% of patients, step-up dose 2 in 19.1%, first treatment dose in 7.1%, and subsequent dose in 1.6% of patients [BRAND-X PM/ p.16 E]

[Call out]
Counsel patients to seek medical attention should signs or symptoms of adverse reaction-x occur. At the first sign of CRS, evaluate patients immediately for hospitalization [BRAND-X PM/ p.16 F]

[Table title]
Recommendations for the management of adverse reaction-x [BRAND-X PM/ p.7 C]

[Table] [BRAND-X PM/ p.7 C]

Grade*	Presenting Symptoms	Actions
Grade 1	Temperature ≥38°C†	• Withhold BRAND-X until adverse reaction-x resolves. ‡
Grade 2	Temperature ≥38°C with either: • Hypotension responsive to fluid and not requiring vasopressors, and/or • Oxygen requirement of low-flow nasal cannula§ or blow-by	• Withhold BRAND-X until adverse reaction-x resolves. ‡ • Monitor patient daily for 48 hours following the next dose of BRAND-X. Instruct patients to remain within proximity of a healthcare facility.

Grade*	Presenting Symptoms	Actions
Grade 3	Temperature ≥38°C with either: • Hypotension requiring one vasopressor with or without vasopressin, and/or • Oxygen requirement of high-flow nasal cannula§, facemask, non-rebreather mask, or Venturi mask	**First occurrence:** • Withhold BRAND-X until adverse reaction-x resolves. ‡ • Provide supportive therapy, which may include intensive care. • Monitor patient daily for 48 hours following the next dose of BRAND-X. Instruct patients to remain within proximity of a healthcare facility. **Recurrent:** • Permanently discontinue therapy with BRAND-X. • Provide supportive therapy, which may include intensive care.
Grade 4	Temperature ≥38°C with either: • Hypotension requiring multiple vasopressors (excluding vasopressin), and/or • Oxygen requirement of positive pressure (e.g., CPAP, BiPAP, intubation, and mechanical ventilation)	• Permanently discontinue therapy with BRAND-X. • Provide supportive therapy, which may include intensive care.

[Abbreviations]
BiPAP=bilevel positive airway pressure; CPAP=continuous positive airway pressure;

[Footnotes] [BRAND-X PM/ p.8 B]
* Based on American Society for Transplantation and Cellular Therapy 2019 grading.
† Fever may not always be present concurrently with hypotension or hypoxia as it may be masked by interventions such as antipyretics or anti-cytokine therapy.
‡ See recommendations in page 11 on restarting BRAND-X after dose delays.
§ Low-flow nasal cannula is ≤6 L/min, and high-flow nasal cannula is >6 L/min.

6.0 MANAGING ADVERSE REACTIONS
[PAGE 9]

[Eyebrow/Tab]
Management of neurologic toxicity

[Headline]
Management of neurologic toxicity, including adverse reaction-y in patients treated with BRAND-X[1]

[Copy]
Neurologic toxicity in BRAND-X-treated patients:

- BRAND-X can serious or life-threatening neurologic toxicity, including adverse reaction-y [BRAND-X PM/ p.17 A]
- Neurologic toxicity occurred in 59% of patients and included headache (18%), encephalopathy (14%), sensory neuropathy (13%), motor dysfunction (14%), adverse reaction-y (3.3%), and Guillain-Barre Syndrome (0.5%) [BRAND-X PM/ p.17 B-D]
- ICANS occurred after step-up dose 1 in 2.7% of patients, after step-up dose 2 in 0.5%, and after subsequent dose in 0.5% of patient BRAND-X PM/ p.17 E]
- Counsel patients to seek medical attention should signs or symptoms of neurologic toxicity occur. Monitor patients for signs and symptoms. At the first sign of neurologic toxicity, evaluate and treat patients immediately based on severity [BRAND-X PM/ p.17 F]

[Table title]
Recommendations for Management of adverse reaction-y [BRAND-X PM/ p.8 A]

[Table] [BRAND-X PM/ p.8 A]

Grade*	Presenting Symptoms†	Actions
Grade 1	ICE score 7-9‡ or depressed level of consciousness§: awakens spontaneously.	• Withhold BRAND-X until adverse reaction-y resolves‖. • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management. • Consider non-sedating, anti-seizure medicinal products (e.g., levetiracetam) for seizure prophylaxis.

Grade*	Presenting Symptoms†	Actions
Grade 2	ICE score 3-6‡ or depressed level of consciousness§: awakens to voice.	• Withhold BRAND-X until adverse reaction-y resolves‖. • Administer dexamethasone¶ 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management. • Consider non-sedating, anti-seizure medicinal products (e.g., levetiracetam) for seizure prophylaxis. • Monitor patient daily for 48 hours following the next dose of BRAND-X ‖. Instruct patients to remain within proximity of a healthcare facility.
Grade 3 (First occurrence)	ICE score 0-2‡ or depressed level of consciousness§: awakens only to tactile stimulus, or seizures§, either: • any clinical seizure, focal or generalized, that resolves rapidly, or • non-convulsive seizures on electroencephalogram (EEG) that resolve with intervention, or raised intracranial pressure: focal/local edema on neuroimaging§	• Withhold BRAND-X until adverse reaction-y resolves‖. • Administer dexamethasone¶ 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management. • Consider non-sedating, anti-seizure medicinal products (e.g., levetiracetam) for seizure prophylaxis. • Provide supportive therapy, which may include intensive care. • Monitor patient daily for 48 hours following the next dose of BRAND-X ‖. Instruct patients to remain within proximity of a healthcare facility.

Grade*	Presenting Symptoms†	Actions
Grade 3 (recurrent)	ICE score 0-2‡ or depressed level of consciousness§: awakens only to tactile stimulus, or seizures§, either: • any clinical seizure, focal or generalized, that resolves rapidly, or • non-convulsive seizures on electroencephalogram (EEG) that resolve with intervention, or raised intracranial pressure: focal/local edema on neuroimaging§	• Permanently discontinue BRAND-X • Administer dexamethasone¶ 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management. • Consider non-sedating, anti-seizure medicinal products (e.g., levetiracetam) for seizure prophylaxis. • Provide supportive therapy, which may include intensive care.

Grade*	Presenting Symptoms†	Actions
Grade 4	ICE score 0‡ or depressed level of consciousness§ either: • patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse, or • stupor or coma, or seizures§, either: • life-threatening prolonged seizure (>5 minutes), or • repetitive clinical or electrical seizures without return to baseline in between, or motor findings§: • deep focal motor weakness such as hemiparesis or paraparesis, or raised intracranial pressure / cerebral oedema§, with signs/symptoms such as: • diffuse cerebral oedema on neuroimaging, or • decerebrate or decorticate posturing, or • cranial nerve VI palsy, or • papilledema, or • Cushing's triad	• Permanently discontinue BRAND-X • Administer dexamethasone¶ 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. • Alternatively, consider administration of methylprednisolone 1,000 mg per day intravenously for 3 days. • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management. • Consider non-sedating, anti-seizure medicinal products (e.g., levetiracetam) for seizure prophylaxis. • Provide supportive therapy, which may include intensive care.

[Eyebrow/Tab]
Management of infections

[Headline]
Infections in patients treated with BRAND-X [1]

[Copy]

Infections in BRAND-X -treated patients:

- Serious infections, including opportunistic infections, occurred in 41.5% of patients, with Grade 3 or 4 infections in 31.1%, and fatal infections in 6.6% [BRAND-X PM/ p.16 H]
- Do not initiate BRAND-X in patients with active infections. Monitor patients for signs and symptoms of infection prior to and during treatment and treat appropriately. Withhold BRAND-X based on severity [BRAND-X PM/ p.16 G]

[Footnotes] [BRAND-X PM/ p.11 A]

* Based on American Society for Transplantation and Cellular Therapy (ASTCT) 2019 grading for ICANS.

† Management is determined by the most severe event, not attributable to any other cause.

‡ If patient is arousable and able to perform Immune Effector Cell-Associated Encephalopathy (ICE) Assessment, assess: Orientation (oriented to year, month, city, hospital = 4 points); Naming (name 3 objects, e.g., point to clock, pen, button = 3 points); Following Commands (e.g., "show me 2 fingers" or "close your eyes and stick out your tongue" = 1 point); Writing (ability to write a standard sentence = 1 point; and Attention (count backwards from 100 by ten = 1 point). If patient is unarousable and unable to perform ICE Assessment = 0 points.

§ Not attributable to any other cause.

‖ See section 7 for recommendations on restarting BRAND-X after dose delays.

¶ All references to dexamethasone administration are dexamethasone or equivalent.

7.0 DOSING
[PAGE 10]

[Headline]
Reduce BRAND-X dosing to every 2 weeks in responding patients after 24 weeks[1] [BRAND-X PM/ p.5 A]

[Table title]
BRAND-X dosing schedule: step-up dose is followed by treatment dose [BRAND-X PM/ p.5 B]

[Table] [BRAND-X PM/ p.5 B]

Dosing Schedule	Week / Day	Dose	
Step-up dosing*†	Week 1: Day 1	Step-up dose 1	12 mg SC
	Week 1: Day 4	Step-up dose 2	32 mg SC
Weekly dosing*‡§	Week 2–4: Day 1	Treatment dose	76 mg SC once weekly
Biweekly dosing§¶	Week 25 onward: Day 1	Treatment dose	76 mg SC once every two weeks

[Copy]
- Premedication is required approximately 1 hour before step-up dose 1, step-up dose 2, and the first full treatment dose: [BRAND-X PM/ p.13 C]
  - acetaminophen (or equivalent) 650 mg orally
  - dexamethasone (or equivalent) 20 mg orally or intravenously
  - diphenhydramine (or equivalent) 25 mg orally
- Monitor patients daily for 48 hours after step-up dose 1 or 2 for signs and symptoms of CRS, or alternatively consider hospitalization [BRAND-X PM/ p.14 A]

[Abbreviation]
SC=subcutaneous.

[Footnotes] BRAND-X PM/ p.6 B]
* Administer premedications prior to the first three doses of BRAND-X.
† A minimum of 2 days should be maintained between step-up dose 1 and 2.
‡ A minimum of 3 days should be maintained between step-up dose 2 and the first full treatment dose.
§ Maintain a minimum of 6 days between treatment doses.
¶ For patients who have achieved and maintained a partial response or better for 2 months.

7.0 DOSING
[PAGE 11]

[Eyebrow/Tab]
Restarting BRAND-X

[Headline]
Restarting BRAND-X after dosage delay[1] [BRAND-X PM/ p.6 A]

[Table] [BRAND-X PM/ p.6 A]

Last administered dose	Duration of delay from the last dose	Action
Step-up dose 1	≤14 days	Restart BRAND-X at step-up dose 2.* If tolerated, increase to 76 mg 4 days later.
	>14 days	Restart BRAND-X at step-up dose 1.*
Step-up dose 2	≤14 days	Restart BRAND-X at 76 mg.
	Between 15 and 28 days	Restart BRAND-X at step-up dose 2.* If tolerated, increase to 76 mg 1 week later.
	>28 days	Restart BRAND-X at step-up dose 1.*
Any full treatment dose	≤42 days	Restart BRAND-X at 76 mg.
	Between 43 and 84 days	Restart BRAND-X at step-up dose 2.* If tolerated, increase to 76 mg 1 week later.
	>84 days	Restart BRAND-X at step-up dose 1.*

[Eyebrow/Tab]
Dosage modifications

[Copy]
Dosage modifications:

- Dosage modifications are necessary to manage adverse reactions [BRAND-X PM/ p.12 A; p.7 C, p.8 A]
- Dosage reduction is not recommended [BRAND-X PM/ p.7 A]
- Dose delays may be required to manage toxicities [BRAND-X PM/ p.7 B]

[Table title]
Recommended dosage modifications for infections, hematologic-, and other non-hematologic adverse reactions [BRAND-X PM/ p.12 A]

[Table] [BRAND-X PM/ p.12 A]

Adverse Reactions	Severity	Actions
Hematologic adverse reactions	Absolute neutrophil count less than 0.5 X 10^9/L	• Withhold BRAND-X until absolute neutrophil count is 0.5 X 10^9/L or higher.
	Febrile neutropenia	• Withhold BRAND-X until absolute neutrophil count is 1 x 10^9/L or higher and fever resolves.
	Hemoglobin less than 8 g/dL	• Withhold BRAND-X until hemoglobin is 8 g/dL or higher.
	Platelet count less than 25,000/mcL Platelet count between 25,000/mcL and 50,000/mcL with bleeding	• Withhold BRAND-X until platelet count is 25,000/mcL or higher and no evidence of bleeding.
Infections and other non-hematologic adverse reactions†	Grade 3	• Withhold BRAND-X until recovery to ≤Grade 1 or baseline.
	Grade 4	• Consider permanent discontinuation of BRAND-X • If BRAND-X is not permanently discontinued, withhold subsequent treatment doses of BRAND-X (e.g., doses administered after BRAND-X step-up dosing schedule) until adverse reaction improves to Grade 1 or less.

[Footnotes]

* Administer premedications prior to the BRAND-X dose. [BRAND-X PM/ p.6 B]

† Based on National Cancer Institute Common Terminology Criteria for Adverse Events, Version 5.0. [BRAND-X PM/ p.12 C]

8.0 BRAND-X ACCESS AND STORAGE

[PAGE 12]

BRAND-X storage and handling:[1] [BRAND-X PM/ p.25 A]

- Store at 2°C to 8°C in the original carton until time of use to protect from light [BRAND-X PM/ p.25 A]
- Do not freeze or shake the vial or carton [BRAND-X PM/ p.25 B]
- Once punctured, the vial and dosing syringe should be used immediately. If the prepared dosing syringe is not used immediately, store syringe between 2°C to 30°C for a maximum of 24 hours [BRAND-X PM/ p.25 C]

9.0 PATIENT SUPPORT PROGRAM
[PAGE 12]

- PSP overview (core messaging)
- Link to the enrollment form

10.0 SUMMARY

[PAGE 13]

Consider BRAND-X , a AAAA- and CD#- directed bispecific antibody [BRAND-X PM/ p.4 D] to treat adult patients with relapsed or refractory Disease-Z:[1] [BRAND-X PM/ p.27 A]

- Ready-to-use subcutaneous administration [BRAND-X PM/ p.13 A, B]
    - Biweekly dosing after 24 weeks in responding patients* [BRAND-X PM/ p.5 A]
- Efficacy Data
    - 61% and 27.6% of AAAA-directed therapy-naïve patients showed an objective response rate [BRAND-X PM/ p.29 A] and complete response rate [BRAND-X PM/ p.29 B], respectively
- Safety Profile
    - Studied in a range of patients [BRAND-X PM/ p.28 A-F]
    - The most frequent adverse reactions of any grade were CRS, anaemia, neutropenia, fatigue, diarrhea, thrombocytopenia, lymphopenia, decreased appetite, rash, arthralgia, nausea, hypokalemia, pyrexia, injection site reaction, and dry skin [BRAND-X PM/ p.19 B]

[Abbreviation]

AAAA=Lorem ipsum dolor sit amet.

[Footnote]

* For patients who have received at least 24 weeks of treatment and have achieved a response (i.e., a partial response or better that has been maintained for at least 2 months), the dose frequency can be reduced from every week to every other week from Week 25. [BRAND-X PM/ p.5 A]

11.0 IMPORTANT SAFETY INFORMATION
[PAGE 14]

Indications:[1] [BRAND-X PM/ p.4 A, B, C]

- BRAND-X is a (AAAA)-directed and CD#-directed bispecific antibody indicated as monotherapy for the treatment of adult patients with relapsed or refractory Disease-Z who have received at least 3 prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD#8 monoclonal antibody, and who have demonstrated disease progression on the last therapy. [BRAND-X PM/ p.4 A]
- Pediatrics (<18 years of age): Not authorized as an indication in Canada. [BRAND-X PM/ p.4 E]
- Geriatrics (≥65 years of age): Evidence from clinical studies does not suggest that use in the geriatric population is associated with differences in safety or effectiveness. [BRAND-X PM/ p.4 F]

Most serious warnings and precautions:[1]
Cytokine Release Syndrome (CRS): adverse reaction-x including life-threatening or fatal reactions, can occur in patients receiving BRAND-X. Initiate treatment with BRAND-X step-up dosing schedule to reduce the risk of CRS. Withhold BRAND-X until adverse reaction-x resolves or permanently discontinues based on severity. [BRAND-X PM/ p.4 B]

Neurologic toxicity: Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious and life-threatening reactions, can occur with BRAND-X. Monitor patients for signs and symptoms of neurologic toxicity, including ICANS, during treatment. Withhold BRAND-X until the neurologic toxicity resolves or permanently discontinue based on severity. [BRAND-X PM/ p.4 C]

Other relevant warnings and precautions:[1] [BRAND-X PM/ p.15 section7]

- Driving and operating machinery [BRAND-X PM/ p.15 A]
- Neutropenia and febrile neutropenia [BRAND-X PM/ p.15 B]
- Hepatoxicity [BRAND-X PM/ p.15 D]
- Concomitant use of Live Viral Vaccines [BRAND-X PM/ p.15 C]
- Hypogammaglobulinemia [BRAND-X PM/ p.14 A]
- Severe, life-threatening, or fatal infections [BRAND-X PM/ p.14 B]
- Hepatitis B virus reactivation [BRAND-X PM/ p.17 G]
- Fertility [BRAND-X PM/ p.18 B], reproductive potential [BRAND-X PM/ p.18 A], pregnancy [BRAND-X PM/ p.18 C] and breastfeeding [BRAND-X PM/ p.18 D]

For more information:
Please consult the product monograph at http:XXXX for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece. The product monograph is also available by calling us at 1-800-XXX-XXXX

12.0 REFERENCE
[PAGE 16]

[Reference]
Reference: 1. BRAND-X (Loremipsum) Product Monograph. <Pharma-Y>. <Date>.

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