Program/Protocol No.: ZW25 Expanded Access Program	Subject ID: ____ ____ ____ ____ - ____ ____ ____ ____ Site / Subject Number

A. GENERAL INFORMATION

Awareness date of the event: |_|_|_|_|_|_|_|_|_| DD MMM YYYY

Type of report: ☐ Initial Report ☐ Follow-up Report No.: ________

Country of occurrence: ______________________________

Investigator Name: ______________________________

Site address: ______________________________

____

____

Phone No: ____________ Fax No: ____________

Email: ______________________________

If reporter is different from Investigator:

Reporter's Name: ______________________________

Phone No: ____________ Fax No: ____________

Email: ______________________________

☐ Physician ☐ Pharmacist ☐ Nurse ☐ Study Coordinator

☐ Other, specify: ______________________________

B. SUBJECT INFORMATION

Sex	Year of Birth	Age at Onset	Ethnicity	Race	
☐ Male ☐ Female ☐ Other	________ YYYY	____ Years	☐ Hispanic/ Latino ☐ Not Hispanic/ Latino ☐ Unknown ☐ Not Reportable	☐ White/Caucasian ☐ Black/African American ☐ American Indian/Alaska Native ☐ Asian ☐ Native Hawaiian/Other Pacific Islander ☐ Not Reportable ☐ Unknown ☐ Other	**Weight:** ______.____ ☐ kg ☐ lb **Height:** ______.____ ☐ cm ☐ in

C. ADVERSE EVENT INFORMATION

Are any Events associated with pregnancy? ☐ Yes ☐ No ☐ Unknown

Adverse Event(s) Report PRIMARY DIAGNOSIS, if known. Otherwise, list symptoms in order of clinical significance.	**Onset / End Date**	**Causality** Causal relationship between study drug and event?	**Outcome**	**Seriousness Criteria** Select all that apply
☐ Event term has changed from previous report ------------------------ **Intensity/Severity:** ☐ NCI-CTCAE Grade 1 ☐ NCI-CTCAE Grade 2 ☐ NCI-CTCAE Grade 3 ☐ NCI-CTCAE Grade 4 ☐ NCI-CTCAE Grade 5	Event Onset Date: ____-____-____ DD MMM YYYY Event End Date: ____-____-____ DD MMM YYYY	ZW25: ☐ Related ☐ Unrelated Alternate Etiology if Not Related to Study Drug:	☐ Recovered / Resolved ☐ Recovering / Resolving ☐ Not Recovered / Not Resolved ☐ Recovered / Resolved w/ Sequelae ☐ Fatal ☐ Unknown	☐ Fatal ☐ Life-threatening ☐ Hospitalization Initial/Prolonged ☐ Disability / Incapacity ☐ Congenital Anomaly/Birth Defect ☐ Medically Significant
☐ Event term has changed from previous report ------------------------ **Intensity/Severity:** ☐ NCI-CTCAE Grade 1 ☐ NCI-CTCAE Grade 2 ☐ NCI-CTCAE Grade 3 ☐ NCI-CTCAE Grade 4 ☐ NCI-CTCAE Grade 5	Event Onset Date: ____-____-____ DD MMM YYYY Event End Date: ____-____-____ DD MMM YYYY	ZW25: ☐ Related ☐ Unrelated Alternate Etiology if Not Related to Study Drug:	☐ Recovered / Resolved ☐ Recovering / Resolving ☐ Not Recovered / Not Resolved ☐ Recovered / Resolved w/ Sequelae ☐ Fatal ☐ Unknown	☐ Fatal ☐ Life-threatening ☐ Hospitalization Initial/Prolonged ☐ Disability / Incapacity ☐ Congenital Anomaly/Birth Defect ☐ Medically Significant
☐ Event term has changed from previous report ------------------------ **Intensity/Severity:** ☐ NCI-CTCAE Grade 1 ☐ NCI-CTCAE Grade 2 ☐ NCI-CTCAE Grade 3 ☐ NCI-CTCAE Grade 4 ☐ NCI-CTCAE Grade 5	Event Onset Date: ____-____-____ DD MMM YYYY Event End Date: ____-____-____ DD MMM YYYY	ZW25: ☐ Related ☐ Unrelated Alternate Etiology if Not Related to Study Drug:	☐ Recovered / Resolved ☐ Recovering / Resolving ☐ Not Recovered / Not Resolved ☐ Recovered / Resolved w/ Sequelae ☐ Fatal ☐ Unknown	☐ Fatal ☐ Life-threatening ☐ Hospitalization Initial/Prolonged ☐ Disability / Incapacity ☐ Congenital Anomaly/Birth Defect ☐ Medically Significant

Hospitalization Dates (if applicable)

Admission Date: |_|_|_|_|_|_|_|_|_| DD MMM YYYY

Discharge Date: |_|_|_|_|_|_|_|_|_| DD MMM YYYY

If outcome is Death

Date of Death: |_|_|_|_|_|_|_|_|_| DD MMM YYYY

Autopsy done? ☐ Yes (attach report) ☐ No

Cause of Death (required): ______________________________

Program/Protocol No.: ZW25 Expanded Access Program	Subject ID: ____ ____ _____ _____ - _____ _____ _____ _____ (Site / Subject Number)

D. STUDY DRUG INFORMATION: ZW25 (zanidatamab)

Study Drug Start Date:	Indication for use:	Batch/Lot Number:	Targeted Dose (mg/kg):	Total Dose (mg):	Route:	Frequency:
DD MMM YYYY					IV	

Date of Last Administration Before Onset:

DD MMM YYYY Cycle: _____ Day:_____ ☐ Not Applicable ☐ Unknown

ACTION TAKEN (STUDY DRUG)

☐ None / dose not changed
☐ Drug withdrawn
☐ Dose temporarily interrupted
☐ Dose reduced

on: DD MMM YYYY ____:____ hh mm

If drug temporarily interrupted & restarted, Resume date: DD MMM YYYY ____:____ hh mm

If dose reduced, Prior Dose:_____ - New Dose:_____

☐ Not applicable (please clarify if pre-treatment event, drug withdrawn prior to event, treatment complete prior to event, etc.): _____

Specify AE leading to "Action Taken":

STUDY DRUG CHALLENGE / RE-CHALLENGE ASSESSMENT

If study drug was withdrawn or dose interrupted, did the event abate? ☐ No ☐ Yes ☐ Not Applicable ☐ Unknown

If study drug was resumed, did the event reappear? ☐ No ☐ Yes ☐ Not Applicable ☐ Unknown

E. RELEVANT TESTS / LABORATORY DATA *(include test results and dates)* ☐ Not Applicable ☐ Relevant Tests/Laboratory Data Attached

Test	Date (DD-MMM-YYYY)	Value	Unit	Reference Range

F. RELEVANT MEDICAL HISTORY *(Please attach additional pages of the Safety Report Form as necessary)* ☐ Not Applicable

Verbatim	Start Date (DD-MMM-YYYY)	Stop Date (DD-MMM-YYYY)	or Check if continuing
			☐
			☐
			☐
			☐
			☐

G. CONCOMITANT MEDICATIONS AT TIME OF EVENT *(Please attach additional pages of the Safety Report Form as necessary)*

Drug Name	Dose/Units	Freq.	Route	Indication	Start Date (DD-MMM-YYYY)	Stop Date (DD-MMM-YYYY)	or Check if continuing
							☐
							☐
							☐
							☐
							☐

Program/Protocol No.:	Subject ID:
ZW25 Expanded Access Program	____ ____ _____ _____ - _____ _____ _____ _____
	Site Subject Number

H. CASE DESCRIPTION *(Please attach additional pages of the Safety Report Form as necessary)*

Please provide a case description and clinical course of the event(s), including any treatment received and/or relevant diagnostic results as applicable.

INVESTIGATOR'S / AUTHORIZED PRINTED NAME	INVESTIGATOR'S / AUTHORIZED SIGNATURE	*DD MMM YYYY* DATE SIGNED

(If reporter is different from Investigator)

REPORTER'S PRINTED NAME	REPORTER'S SIGNATURE	*DD MMM YYYY* DATE SIGNED

Please return completed forms to PRA Pharmacovigilance and Patient Safety:

North / South America
Fax: 1-888-772-6919 or 1-434-951-3482
Email: drugsafety@zymeworks.com

Europe, Asia, Pacific & Africa
Fax: +44 1792 525 720
Email: drugsafety@zymeworks.com