PREGNANCY REPORT FORM

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

A. GENERAL INFORMATION

Date of report: |_|_|_|_|_|_|_|_|_| (DD MMM YYYY)

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

Country: _____

Principal Investigator's Name: _____

Site address: _____

_____

_____

Phone No: _____ Fax No: _____

Email: _____

If reporter is different from Principal 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 ☐ Asian ☐ American Indian/Alaska Native ☐ Native Hawaiian/Other Pacific Islander ☐ Not Reportable ☐ Unknown ☐Other	**Weight:** _____.____ ☐ kg ☐ lb **Height:** _____.____ ☐ cm ☐ in

MAINTERNAL INFORMATION (Complete section only if female partner of male subject) ☐Maternal Data Consent obtained (if applicable)

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

C. PREVIOUS PREGNANCY INFORMATION (HISTORY)

Pregnancy Number	Year of Outcome (YYYY)	Previous Pregnancy Birth Type (Fill in number)	Birth Type Options	Previous Pregnancy Fetal Outcome (Fill in number)	Fetal Outcome Options
		Birth Type [ ]	1. Spontaneous Abortion/Miscarriage 2. Elective Abortion 3. Pre Term 4. Post Term 5. Full Term 6. Stillbirth/Intrauterine Death 7. Unknown	Outcome [ ]	1. Normal 2. Prenatal Complication 3. Perinatal Complication 4. Postnatal Complication
		Birth Type [ ]		Outcome [ ]	
		Birth Type [ ]		Outcome [ ]	
		Birth Type [ ]		Outcome [ ]	

D. CURRENT PREGNANCY INFORMATION

Date of Last Menstrual Period |_|_|_|_|_|_|_|_|_| (DD MMM YYYY)

Expected Date of Delivery |_|_|_|_|_|_|_|_|_| (DD MMM YYYY)

Number of fetuses: _____

Gestation period (when event/reaction observed in fetus): _____

Gestation period Unit: _____

Neonate Number	Delivery Type (Cesarean/Vaginal)	Birth Type (Select from above options)	Fetal Outcomes (Select from above options)	Weight	Height	APGAR Score (1/5/10 minutes)	Sex
				☐ kg ☐ lb	☐ cm ☐ in		☐ Male ☐ Female
				☐ kg ☐ lb	☐ cm ☐ in		☐ Male ☐ Female
				☐ kg ☐ lb	☐ cm ☐ in		☐ Male ☐ Female

Relevant **Maternal Medical History** (include **risk factors/exposure** from illnesses, occupation, medicinal products(s) and/or hereditary disease):

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E. STUDY DRUG INFORMATION: ZW25 (zanidatamab)

☐ Not Available / Not Applicable

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

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.)**:** _____

_____

F. CONCOMITANT MEDICATIONS

☐ Please attach additional pages of the Pregnancy Report Form as necessary
☐ Not Available / Not Applicable

Drug Name	Dose/Unit	Freq.	Route	Indication	Start Date (DD-MMM-YYYY)	Stop Date (DD-MMM-YYYY)	Ongoing
							☐
							☐
							☐
							☐

G. ADDITIONAL INFORMATION / DETAILS

Please add any medically relevant information e.g. diagnostic / laboratory / screening tests and results; maternal and fetal observations, complications etc.
Any adverse event(s) must be reported via the Safety Report Form.

_____ _____ DD MMM YYYY

INVESTIGATOR'S / AUTHORIZED PRINTED NAME | INVESTIGATOR'S / AUTHORIZED SIGNATURE | DATE SIGNED

(If reporter is different from Investigator)

_____ _____ DD MMM YYYY

REPORTER'S PRINTED NAME | REPORTER'S SIGNATURE | 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