Serious Adverse Event Report Form

AER # (insert when known): 2 0 2 0 2 2 9 0 4 6

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PROTOCOL #

SUBJECT # 1 0 1 2 1 0 0 4

Protocol Title: Phase 3/4 randomized safety endpoint study of 2 doses of Tofacitinib in comparison to a tumor necrosis factor (TNF) inhibitor in subjects with Rheumatoid arthritis.

☐ **Initial Report** ☒ **Follow-Up Report** Data Entry Mode: Electronic **Country where event occurred:** Mexico

Patient Data ☐ Male ☒ Female Date of Birth 07 - Jan - 1964 (DD-MMM-YYYY) Weight ☐ lb ☒ kg Height 165 ☐ in ☒ cm

Ethnicity: ☐ Asian ☐ Black ☐ Hispanic ☐ Native American ☐ White ☐ Other, specify ☐ Cannot ask per local regulations

If patient has died: Date of Death 06 - Apr - 2020 (DD-MMM-YYYY) Cause of Death: ☐ Disease Progression ☒ Other, specify: Pneumonia Positive SARS-CoV-2 (PCR)

Was autopsy performed? ☐ Yes ☐ No ☐ Unknown If yes, what was the autopsy determined cause of death:

Patient's Past Medical History
☐ None
☐ Unknown

Provide relevant past medical history below. Include all other illnesses present at time of event. End of event(s) is date of death if due to event, date of recovery or recovery with sequelae (of last event if multiple events), or date patient's condition stabilized.
If more space is needed, use supplemental page, and check this box: ☐

Illness	Onset Date DD-MMM-YYYY	Stop Date DD-MMM-YYYY *If no Stop Date, check box if ongoing at time of last observation during or at end of event(s)*	Pertinent Details *Include surgical procedures and dates*
Recurrent tonsillitis	XX-XXX-1973	XX-XXX-1973 ☐	Tonsillectomia (1973)
Hallux Valgus deformity	XX-XXX-2011	XX-XXX-2011 ☐	Surgical Repair (2011)
Pectic Ulser disease	24-Feb-2014	- - ☒	Controlled with Pharmacological Treatment
Depression	24-Feb-2014	- - ☒	Controlled with Pharmalogical treatment.
Rheumatoid Arthritis	06-Jan-2014	- - ☒	Controlled with Pharmalogical treatment.
Sjögren Syndrome	24-Jun-2014	- - ☐	Controlled with Pharmalogical treatment.
	- -	- - ☐	
	- -	- - ☐	

Relevant Tests
☐ None
☐ Unknown

List only relevant diagnostic and confirmatory test results for event(s), for example, from blood tests, diagnostic imaging
If more space is needed, use supplemental page, and check this box: ☐

Test	Date DD-MMM-YYYY	Result	Units	Normal Range Low	Normal Range High	Comments
Rheumatoid Factor	25-Jun-2015	103	UI/ml			Positive higher titers of 20.
Anti-CCP	25-Jun-2015	Positive		Negativo		Positive qualitativa
	- -					
	- -					
	- -					
	- -					
	- -					

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2	0	2	0	2	2	9	0	4	6

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SUBJECT # 1 0 1 2 1 0 0 4

Narrative *Provide any information regarding the circumstances, sequence, diagnosis and treatment of the event(s) not otherwise reported on this form. Include details of previous treatments with the study drugs. Complete once only for each report; do not repeat for each event. If more space is needed, use additional copies of this page and check this box*
If additional space is needed, use supplemental page, and check this box: ☐

Changes were made to Infrom.

the correct data for patient 10121004 is:

Study drug from:

30Jul2015 to 21Feb2018

08Mar2018 to 20Feb2019

21Feb2019 to 23Mar2020

The patient took his last dose on 23 / Mar / 2020
On 24 / Mar / 2020 he attended his end of study visit, the day on which the study drug was suspended.

AE Action Study Drug

The subject completed the study drug treatment according to protocol on 23Mar2020 prior to the onset of this event on 01
Apr2020. The subject was still on study until completion of end of study visit on 21Apr2020. The end of study visit was not performed since the subject died on 06Apr2020. Subject was withdrawn from the study on this date"

Reporter Comments:

Reporter: Ana Gladis (First Name) Loya Flores (Last Name *Please* PRINT) 15 - Sep 2020 (Date: DD-MMM-YYYY)

Address: Miguel Hidalgo y Costilla (Street) Culiacán (City / State) 15 Maka (Zip Code) 80000 (Country) Mexico.

Telephone: +52 6677 13-67-7 Fax: +52 6677 12-74-74, Email: marcomaradiaga@hotmail.com

Investigator's Name: Marco Maradiaga Cerena

Investigator (or Designee) SAE Awareness Date: 15 - Sep - 2020 (DD-MMM-YYYY)

Investigator or Designee Signature :

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Investigator's Name: Marco Maradiaga Cerena

Investigator (or Designee) SAE Awareness Date: 15 - Sep - 2020 (DD-MMM-YYYY)

Investigator or Designee Signature :