



TasP

Interventional Treatment as Prevention - ANRS 12249
Ukaphila kwami, ukaphila kwethu (no health for our health)

Ukaphila kwami, ukaphila kwethu

Africa Centre TasP Trial

SAE-AC

Serious Adverse Event Reporting



00317300

ANRS 12249 Complementary SAE Notification

Completed forms must be sent to
ANRS within 8 days.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

Initial Notification Date

2015 05 19

i.e. Date of original Initial Notification Form

Complementary Notification Date

2015 08 07

1. Patient details

TasP ID

S 2 9 6 1

Name

Z. P. M.

Sex

Male

☒ Female

Date of birth

1 9 8 3 0 7 0 1

Enrolment date

2 0 1 5 0 4 1 0

2. Description of the reported SAE

Participant previously admitted to hospital with Hb 3g/dl and platelets 5. She was transfused and referred to Regional hospital where she was started on Prednisone and had investigations done and was booked for follow up.

Date of SAE onset 2 0 1 5 0 4 1 6

3. Complementary information

She was reviewed at Regional hospital on 22/7/2015 and admitted as she was actively bleeding from the gums. She was transfused 2 units blood and given Prednisone 60mg daily. At discharge (30/7/2015); Hb was 7.6g/dl and platelets 10. She is on lifelong prednisone - dose adjusted according to platelet levels.

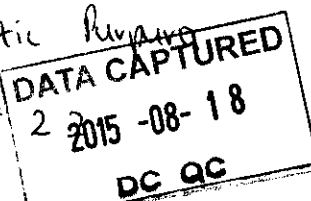
4. New diagnosis?

☒ Yes ☐ Describe
No

Idiopathic Thrombocytopenic Purpura

Date of new diagnosis

2 0 1 5 0 7



5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

Yes No ☒ N/A

Which treatment?

Date discontinued

b) Did the event reappear after reintroduction of treatment?

Yes No ☒ N/A

Which treatment?

Date reintroduced

c) Has the complementary information mentioned above modified your judgement of causality regarding one or more treatments compared to your initial notification?

Yes ☐ Section 6

☒ No ☐ Section 7

6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

<u>Generic Name</u>	<u>Dose</u>	<u>Frequency</u>	<u>New judgement of causality</u>
1.			Unrelated Poss. related Cannot be assessed
2.			Unrelated Poss. related Cannot be assessed
3.			Unrelated Poss. related Cannot be assessed
4.			Unrelated Poss. related Cannot be assessed

7. Other causes of SAE, if unrelated to drugs mentioned in Section 6 above

7a. According to the physician, is this SAE likely to be related to participation in the research?

Yes ☐ No ☒

7b. According to the physician, is this SAE related to any causes other than the research?

This includes the patient's medical history

Yes ☐ No ☒
☒ Describe

Patient has been diagnosed with
Idiopathic Thrombocytopenic Purpura.
(Cause unknown)

8. SAE Outcome

Death → Date of death Probable Diagnosis _____

Unknown to date

Ongoing

Improved

Worsened

☒ Recovered → Date of recovery

Recovered without sequelae

or

☒ Recovered with sequelae

Describe Platelets to be monitored and Prednisone dose to be adjusted accordingly.

Physician reporting SAE Complementary Notification

Name GUB'ELINE NIKHULI

Signature

Date form completed 20150807