Tanezumab A4091061 Study Newsletter

September 2017 | Edition 21

Message from the Study Team

Dear Investigators & Site Staff,

In this month's newsletter edition, we would like to highlight some key reminders and provide clarifications to certain areas, including: routine device checks, invoice submission reminders, and the use of opioid-non-opioid drug combinations. If any assistance is required, please reach out to your CRAs and RCSLs. As always, thank you for your continued engagement and efforts in this challenging study.

With gratitude,

The A4091061 Pfizer and inVentiv Team

Site of the Month

Dr. Crihana (Romania) for randomizing their 7th subject!

Breaking News

As of this month, there are currently 78 sites approved for Protocol Amendment 3, 56 of which are active for enrollment under the new amendment. Thank you for your accelerated efforts in completing the implementation activities for Protocol Amendment 3 at your sites!

Study Status/Update

To date (27 Sep 2017), the A4091061 study has 91 subjects screened and 48 subjects randomized.

A4091061 Top Enrollers

Country	PI	Enrollment Status	
		Subjects Screened	Subjects Randomized
Romania	Dr. Carmen Crihana	8	7
South Korea	Dr. Keon Uk Park	6	4
United Kingdom	Dr. Marie Fallon	5	4
Poland	Dr. Marcin Janecki	9	3
Slovakia	Dr. Viliam Cibik	5	3
Poland	Dr. Magdalena Korozan	6	3
Poland	Dr. Maciej Sopata	4	3
Poland	Dr. Tatiana Pietrzynska	6	2

Operational Tips

CRF Health Reminder: Routine Check of Devices

If eDiary and Trial Slate devices are not used for a while, they should be checked regularly to avoid potential issues, such as dead battery, out of date software, or a previous subject remaining "active" when they have actually been deactivated from the study. As good practice, please check your devices **at least every 6 months** to prevent any such issues from occurring.

Invoice Submission Process Reminder

Please ensure that all invoices are submitted to PfizerGrantsandPayments@inventivhealth.com with the following information:

1. The invoice must be billed to the inVentiv legal entity listed in your site's contract.

2. Each invoice MUST contain the following information:

a. Invoice Number

b. Invoice Date

c. Total Amount Payable

d. Principal Investigator Name

e. Institution Name

f. Protocol Number

g. Description of Services Provided

h. Subject Number

i. Banking information

j. Event date (if site submits any invoice for procedures)

Clinical Clarification

Permitted vs. Prohibited Use of Opioid-non-Opioid Drug Combinations

Combination opioid-non-opioid medications (e.g. oxycodone-acetaminophen) are not permitted in study A4091061 as background opioid treatment. Individual components of the drug combination **are** permitted (e.g. acetaminophen used as a separate adjunct to oxycodone), with the exception of NSAIDs.

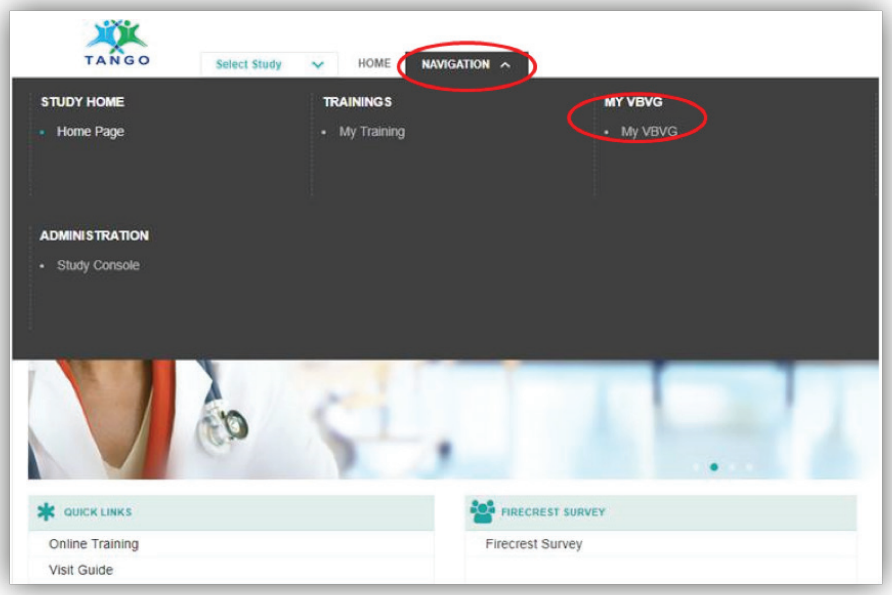
Opioid-non-opioid combination medications **are** permitted **as standard of care analgesia** from the time point permitted per protocol (Week 32 in protocol amendment 2, Week 8 in protocol amendment 3), if the treatment is deemed standard of care analgesia for the site and is approved by the applicable Health Authority for same.

Use of regular NSAIDs (either alone or in combination with opioids) is strictly prohibited throughout the study and up until 16 weeks following the last dose of study medication, regardless of whether the drug is considered standard of care treatment.

Firecrest Update & Reminder

Visit Guide in Firecrest: Updated for PA3

An updated version of the My Visit by Visit Guide (My VBVG) in the Firecrest portal has now been made available. Please refer to this useful guide for each subject study visit. See below for a quick reminder for navigating to this guide within Firecrest:



Top Screen Failure Reasons*

Screen Failure Reason	Number of Instances
Inclusion 13	
Adequate renal function at Screening (confirmed by a repeat test if needed), as defined by: a. Serum creatinine ≤1.5 x upper limit of normal (ULN) or estimated creatinine clearance ≥60 mL/min as calculated using the method standard for the institution, and b. Urinary protein <2+ by urine dipstick. If dipstick is ≥2+, then 24 hour urinary protein <2 g per 24 hours.	9
Inclusion 12	
Adequate bone marrow function at Screening (confirmed by a repeat test if needed), as defined by: a. Absolute Neutrophil Count (ANC) ≥1,500/mm^3 or ≥1.5 x 10^9/L; b. Platelets ≥100,000/mm^3 or ≥100 x 10^9/L; c. Hemoglobin ≥9.0 g/dL.	5
Exclusion 12	
Radiographic (x-ray) evidence of any of the following conditions as determined by the central radiology reviewer and as defined in the tanezumab program imaging atlas at Screening: 1) rapidly progressive osteoarthritis, 2) atrophic or hypotrophic osteoarthritis, 3) subchondral insufficiency fracture, 4) spontaneous osteonecrosis of the knee (SPONK), 5) osteonecrosis, or 6) pathologic fracture. Necrosis of the bone secondary to radiotherapy (ie, osteoradionecrosis) and in relation to metastatic disease of the bone (ie, involving the tumor-bone interface) is allowable. Vertebral pathologic fracture with less than 50% vertebral body destruction and no spinal canal compromise is allowable.	4

*As of 27Sep2017, 36 total Screen Fails.

Who to contact

Bioclinica (Central Imaging)
Tel: US and Canada sites dial: 1-888-ASK-BIO2 (1-888-275-2462)
International sites dial: +1-267-757-3330
Email: Pfizer_aNGF_Support@BioClinica.com

BMS (Biomedical Systems—Central ECG)
Contact available in ECG procedure manual

CRF Health (ePRO)
Website:
https://trialmax.crfhealth.net/manager-2.3.0/PF10068/login.faces.
Tel: Numbers available in the manual
Global helpdesk.
Email: A4091061@stefanini.com

Covance (Central Laboratory)
http://www.covance.com/shipping
Regional Contact available in Lab manual

EDC/OC-RDC Helpdesk
Tel: 1-877-433-2619

Endpoint Mgmt Team (Safety Event Adjudication)
Tel: 267-733-4357
Email: A409Endpoint@inventivhealth.com

inVentiv Health Clinical IRT (IWRS)
Website: https://irt.almacgroup.com
Phone: +1-877-738-8831 / +215-660-8800 (US)
for other countries please refer to the user manual.
Email: ivrssupport@almacgroup.com

Firecrest (Training & Study Portal)
Email: pfizer@firecrestclinical.com
Tel: +353 61 516910/Toll free numbers available at
www.firecrestclinical.com/pfizer

Key study team contacts

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