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CRUSADER

NEWSLETTER

NOVEMBER 2020 ESMO AND IASLC EDITION

MET Crusaders is a community of Lung Cancer patients and care givers collaborating with advocates and medical professionals collectively dedicated to helping patients with a MET alteration live normal lives.

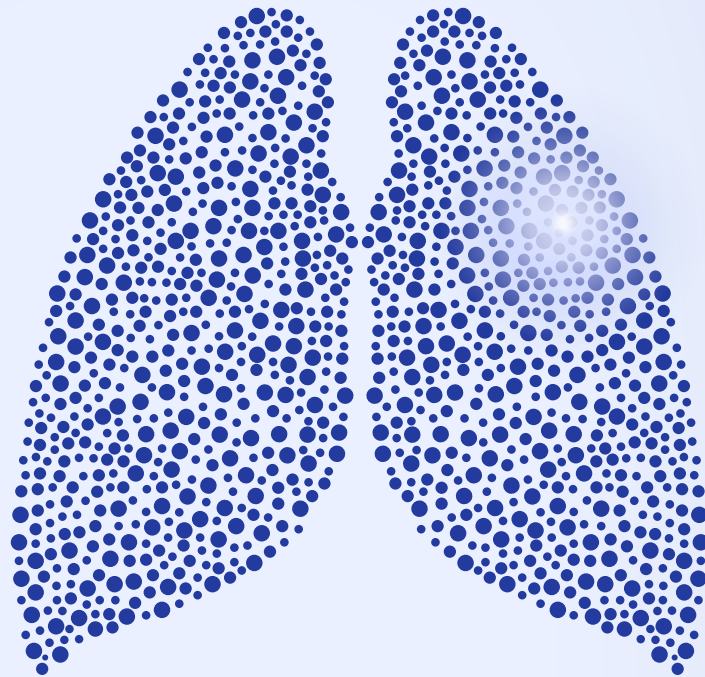
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Tepotinib in patients with advanced NSCLC with MET exon 14 (METex14) skipping - overall efficacy results from VISION cohort A

ESMO Abstract/Poster 1283P Drug: Tepotinib NCT ID: 02864992

Objective:

- To report overall efficacy outcomes of the VISION study, which investigated the safety and efficacy of tepotinib with patients with NSCLC and MET alterations

Design:

- Multi-cohort, phase II study
- Tepotinib 500mg once daily

Population:

- 152 patients with advanced EGFR / ALK wild-type, METex14 skipping NSCLC
- 55% received prior treatment for advanced / metastatic NSCLC

Efficacy Results:

- Overall objective response rate (ORR) = 44.5% according to an independent review committee, 54.8% according to the study investigator
- Median duration of response
 - Alteration confirmed via liquid biopsy = 9.9 months according to an independent review committee, 14 months according to the study investigator
 - Alteration confirmed via tissue biopsy = 12.4 months according to an independent review committee, 16.4 months according to the study investigator

Efficacy Results (cont.):

- Median progression-free survival (PFS)
 - Alteration confirmed via liquid biopsy = 8.5 months according to an independent review committee and study investigator
 - Alteration confirmed via tissue biopsy = 11 months according to an independent review committee, 12.2 months according to the study investigator

Safety Results:

- Grade 3 or higher treatment-related side effects were seen in 27.6% of patients
- 11.2% of patients discontinued tepotinib due to treatment-related side effects, the majority of which was due to peripheral edema (4.6%)

Conclusion:

- Tepotinib is effective with manageable side effects in patients with METex14 NSCLC



Tepotinib exposure–response analyses of safety and efficacy in patients with solid tumors

ESMO Abstract/Poster 584P Drug: Tepotinib

Objective:

- To evaluate the relationship between tepotinib exposure, safety, and efficacy in patients with solid tumors

Design:

- Analysis of results from 5 trials
- Efficacy data obtained from VISION trial (METex14 NSCLC, tepotinib 500mg once daily)
- Patients received between tepotinib 30mg and 1400mg once daily

Population:

- Patients with solid tumors (not just NSCLC)

Efficacy Results:

- No association between tepotinib exposure and response rates or duration of response

Safety Results:

- No association between tepotinib exposure and severity or frequency of edema
- No association between tepotinib exposure and lipase elevations (an indication of injury to the pancreas)
- Trend of increased amylase and liver enzymes did not correlate with level of tepotinib exposure

Conclusion:

- There is no correlation between tepotinib exposure and its safety and efficacy
- Confirms that tepotinib 500mg once daily is an appropriate dose

Activity of tepotinib in brain metastases (BM): preclinical models and clinical data from patients with MET exon 14 (METex14) skipping NSCLC

ESMO Abstract/Poster 1286P Drug: Tepotinib NCT ID: 02864992

Objective:

- To determine the activity of tepotinib in brain metastases

Population:

- Preclinical models (rats, patient-derived tissues with high MET amplification) and patients from VISION study with brain metastases

Results:

- High binding of tepotinib in the brain
- Tumor regression was observed in the patient-derived tissue models

Results (cont.):

- Objective response rate (ORR) = 57.1% according to an independent review committee and 53.8% according to the study investigator

Conclusion:

- Tepotinib caused tumor regression in patient-derived tissue models with lung cancer and a MET alteration
- Activity of tepotinib in patients with brain metastases was similar to the overall population in the VISION study



Biomarker testing patterns and treatment outcomes in patients with advanced non-small cell lung cancer and MET exon 14 skipping mutations

IASLC Abstract MO01.03

Objective:

- To determine biomarker testing patterns and outcomes of treatment with chemotherapy and immunotherapy in patients with advanced MET exon 14 skipping (METex14) non-small cell lung cancer (NSCLC)

Design:

- Descriptive retrospective study

Population:

- 91 patients with advanced METex14 NSCLC

Results:

- 62% of patients received PD-L1 testing
- 60% of patients received next-generation sequencing (NGS) testing within 3 months after diagnosis
- 77% of patients received PD-L1 testing within 3 months after diagnosis

Results (cont.):

- Median real-world progression-free survival (PFS)
 - 5.7 months for patients on first-line chemotherapy
 - 2.4 months for patients on first-line immunotherapy
 - 3.5 months for patients on second-line chemotherapy
 - 4.7 months for patients on second-line immunotherapy
- 3-month real-world PFS rates
 - 78% for patients on first-line chemotherapy
 - 33% for patients on first-line immunotherapy
 - 54% for patients on second-line chemotherapy
 - 67% for patients on second-line immunotherapy

Conclusion:

- Immunotherapy (specifically only one immune-related therapy, as opposed to a combination of therapies) is associated with limited real-world PFS in patients with METex14 advanced NSCLC
- Chemotherapy is also associated with limited real-world PFS in patients with METex14 advanced NSCLC, but to a lesser extent than single-agent immunotherapy

Comparison of clinical outcomes of patients with METex14 NSCLC treated with first-line capmatinib in the GEOMETRY mono-1 study with those of a cohort of real-world patients

ESMO Abstract/Poster 1346P Drug: Capmatinib NCT ID: 02414139

Objective:

- To compare the clinical characteristics, treatment, and outcomes between patients who received capmatinib in the GEOMETRY mono-1 trial to real-world patients who received first-line chemotherapy and/or immunotherapy

Design:

- Retrospective cohort study

Population:

- Patients with advanced / metastatic METex14 NSCLC

Results:

- Median progression-free survival (PFS) = 12 months in GEOMETRY mono-1 trial versus 6.1 months in real-world patients
- Median overall survival (OS) = 20.8 months in GEOMETRY mono-1 trial versus 14.8 months in real-world patients

Conclusion:

- Capmatinib demonstrated longer PFS compared to available first-line treatments for advanced / metastatic NSCLC



Capmatinib in patients with METex14-mutated advanced non-small cell lung cancer who received prior immunotherapy: the phase II GEOMETRY mono-1 study

ESMO Abstract/Poster 1285P Drug: Capmatinib NCT ID: 02414139

Objective:

- To analyze the safety and efficacy of capmatinib in the subgroup of patients who received prior immunotherapy in the GEOMETRY mono-1 study

Design:

- Subgroup analysis comparing 19 patients who received prior immunotherapy to 50 patients who did not receive prior immunotherapy
- Capmatinib 400mg twice daily

Population:

- Patients with pre-treated METex14 NSCLC

Efficacy Results:

- Objective response rate (ORR) of capmatinib was 57.9% in patients who received prior immunotherapy compared to 34% in patients who did not receive prior immunotherapy
- Median duration of response of capmatinib was 11.2 months in patients who received prior immunotherapy compared to 7.16 months in patients who did not receive prior immunotherapy

Safety Results:

- Similar between patients who received prior immunotherapy and those who did not

Conclusion:

- Capmatinib showed efficacy and was well-tolerated regardless of whether or not patients were treated previously with immunotherapy

Health-related quality of life in patients with NSCLC harboring MET exon 14 skipping (METex14) treated with tepotinib

ESMO Abstract/Poster 1347P Drug: Tepotinib NCT ID: 02864992

Objective:

- To assess health-related quality of life in patients with METex14 NSCLC treated with tepotinib

Design:

- Patients completed two questionnaires at baseline and every 6 weeks
- Questionnaires were scored between 0 and 100
- At least a 10 point change in questionnaire scores was deemed clinically meaningful

Population:

- Patients from cohort A in the VISION trial

Results:

- Scores from one of the questionnaires indicated improvement in cough, dyspnea (shortness of breath), and chest pain after 12 weeks and continued through 24 weeks and beyond
- Scores from the other questionnaire remained stable and did not worsen during treatment

Conclusion:

- Patients with advanced METex14 NSCLC maintained their health-related quality of life or had improvement in symptoms (cough, dyspnea, chest pain) while being treated with tepotinib
- These results support treating older patients with METex14 NSCLC with tepotinib



Management of selected adverse events with capmatinib: institutional experiences from the GEOMETRY Mono-1 trial

IASLC Abstract MO01.04 Drug: Capmatinib NCT ID: 02414139

Objective:

- To describe ways to manage adverse effects of capmatinib, including peripheral edema (fluid retention), nausea, and vomiting, experienced by patients enrolled in the GEOMETRY Mono-1 trial

Design:

- Retrospective review from two institutions

Population:

- Metastatic non-small cell lung cancer (NSCLC) with MET exon 14 skipping (METex14)

Results:

- Peripheral edema
 - Generally managed with compression stockings, elevating limbs, and/or diuretics
 - Some patients were referred to a lymphedema clinic and managed with lymphatic massages, prescription-grade compression stockings, and/or stretching exercises
 - Stretching exercises and compression stockings were shown to improve mild lower edema without having to stop capmatinib
 - Edema usually resolved after stopping capmatinib

Results (cont.):

- Nausea/vomiting
 - Some patients experienced nausea/vomiting when taking capmatinib on an empty stomach, others experienced nausea/vomiting when taking capmatinib after eating
 - Management includes anti-nausea medications, either as needed or taking preventatively before taking capmatinib
 - Some patients had to reduce their dose to reduce vomiting
 - Taking capmatinib with food appears to reduce nausea/vomiting

Conclusion:

- Patients on capmatinib who experience edema and nausea/vomiting can be managed successfully in a variety of ways so that they may continue to stay on treatment



MET Clinical Trials

IMPORTANT

Below is a list of clinical trials involving MET alterations on **ClinicalTrials.gov**. This list is a summary snapshot of emerging therapeutic strategies, details of these trials can be found at **ClinicalTrials.gov**. Recruitment for clinical trials is constantly changing, and many eligibility criteria are typically required in order to participate. The treatments being studied in the clinical trials listed here are meant for reference only and do not replace medical advice. Always have a discussion with your oncologist if you have questions about clinical trial participation.

This list was last updated on December 5, 2020.

TKI TRIALS

NIH Identifier: NCT04084717

Link: <https://clinicaltrials.gov/ct2/show/NCT04084717>

Title: Study of Crizotinib for ROS1 and MET Activated Lung Cancer
Status: Recruiting
Drug: Crizotinib
Phase: P2
Countries: Canada

NIH Identifier: NCT03693339

Link: <https://clinicaltrials.gov/ct2/show/NCT03693339>

Title: Capmatinib in Patients With Non-small Cell Lung Cancer Harboring cMET exon14 Skipping Mutation
Status: Recruiting
Drug: Capmatinib
Phase: P2
Countries: Republic of Korea

NIH Identifier: NCT03993873

Link: <https://clinicaltrials.gov/ct2/show/NCT03993873>

Title: Phase 1 Study of TPX-0022, a MET/CSF1R/SRC Inhibitor, in Patients With Advanced Solid Tumors Harboring Genetic Alterations in MET
Status: Recruiting
Drug: TPX-0022
Phase: P1
Countries: US, Republic of Korea

NIH Identifier: NCT02864992

Link: <https://clinicaltrials.gov/ct2/show/NCT02864992>

Title: Tepotinib Phase II in Non-small Cell Lung Cancer (NSCLC) Harboring MET Alterations (VISION)
Status: Recruiting
Drug: Tepotinib
Phase: P2
Countries: US, Austria, Belgium, France, Germany, Israel, Italy, Japan, Republic of Korea, Netherland, Poland, Spain, Switzerland, Taiwan,

NIH Identifier: NCT03175224

Link: <https://clinicaltrials.gov/ct2/show/NCT03175224>

Title: APL-101 Study of Subjects With NSCLC With c-Met EXON 14 Skip Mutations and c-Met Dysregulation Advanced Solid Tumors (SPARTA)
Status: Recruiting
Drug: APL-101
Phase: P2
Countries: US, Australia, Canada, Italy, Puerto Rico, Singapore, Spain, Taiwan, Ukraine, United Kingdom

NIH Identifier: NCT04258033

Link: <https://clinicaltrials.gov/ct2/show/NCT04258033>

Title: A Study of PLB1001 in Non-small Cell Lung Cancer With c-Met Dysregulation
Status: Recruiting
Drug: PLB1001 also known as Bozotinib and APL-101
Phase: P2
Countries: China

NIH Identifier: NCT02920996

Link: <https://clinicaltrials.gov/ct2/show/NCT02920996>

Title: Merestinin In Non-Small Cell Lung Cancer And Solid Tumors
Status: Active, Not Recruiting
Drug: Merestinin
Phase: P2
Countries: US

NIH Identifier: NCT02750215

Link: <https://clinicaltrials.gov/ct2/show/NCT02750215>

Title: A Study of Capmatinib (INC280) in NSCLC Patients With MET Exon 14 Alterations Who Have Received Prior MET Inhibitor
Status: Active, Not Recruiting
Drug: Capmatinib
Phase: P2
Countries: US

NIH Identifier: NCT02414139

Link: <https://clinicaltrials.gov/ct2/show/NCT02414139>

Title: Clinical Study of Oral cMET Inhibitor INC280 in Adult Patients With EGFR Wild-type Advanced Non-small Cell Lung Cancer (Geometry Mono-1)
Status: Recruiting
Drug: Capmatinib
Phase: P2
Countries: US, Argentina, Austria, Belgium, Brazil, Canada, France, Germany, Israel, Italy, Japan, Republic of Korea, Lebanon, Mexico, Netherlands, Norway, Poland, Russia, Singapore, Spain, Sweden, Switzerland, Taiwan, Turkey, United Kingdom

NIH Identifier: NCT01639508

Link: <https://clinicaltrials.gov/ct2/show/NCT01639508>

Title: Cabozantinib in Patients With RET Fusion-Positive Advanced Non-Small Cell Lung Cancer and Those With Other Genotypes: ROS1 or NTRK Fusions or Increased MET or AXL Activity
Status: Recruiting
Drug: Cabozantinib
Phase: P2
Countries: US

NIH Identifier: NCT02219711

Link: <https://clinicaltrials.gov/ct2/show/NCT02219711>

Title: Phase 1/1b Study of MGCD516 in Patients with Advanced Cancer
Status: Active, Not Recruiting
Drug: MGCD516
Phase: P1
Countries: US, Republic of Korea

NIH Identifier: NCT04270591

Link: <https://clinicaltrials.gov/ct2/show/NCT04270591>

Title: Assess the Anti-tumor Activity and Safety of Glumetinib in Patient with Advanced c-MET-positive Non-Small Cell Lung Cancer
Status: Recruiting
Drug: Glumetinib
Phase: P1/P2
Countries: US, China



UMBRELLA TRIALS

NIH Identifier: NCT03574402

Link: <https://clinicaltrials.gov/ct2/show/NCT03574402>

Title: Phase II Umbrella Study Directed by Next Generation Sequencing (TRUMP)
Status: Recruiting
Trial Name: Umbrella (TRUMP)
Phase: P2
Countries: China

NIH Identifier: NCT02693535

Link: <https://clinicaltrials.gov/ct2/show/NCT02693535>

Title: TAPUR: Testing the Use of Food and Drug Administration (FDA) Approved Drugs That Target a Specific Abnormality in a Tumor Gene in People With Advanced Stage Cancer (TAPUR)
Status: Recruiting
Trial Name: TAPUR
Phase: P2
Countries: US

NIH Identifier: NCT02664935

Link: <https://clinicaltrials.gov/ct2/show/NCT02664935>

Title: National Lung Matrix Trial: Multi-drug Phase II Trial in Non-Small Cell Lung Cancer
Status: Recruiting
Trial Name: Matrix
Phase: P2
Countries: United Kingdom

NIH Identifier: NCT02465060

Link: <https://clinicaltrials.gov/ct2/show/NCT02465060>

Title: Targeted Therapy Directed by Genetic Testing in Treating Patients With Advanced Refractory Solid Tumors, Lymphomas, or Multiple Myeloma (The MATCH Screening Trial)
Status: Recruiting
Trial Name: Match
Phase: P2
Countries: US, Quam, Puerto Rico

IMMUNOTHERAPY TRIALS

NIH Identifier: NCT02323126

Link: <https://clinicaltrials.gov/ct2/show/NCT02323126>

Title: Study of Efficacy and Safety of Nivolumab in Combination with EGF816 and of Nivolumab in Combination With INC280 in Patients With Previously Treated Non-small Cell Lung Cancer (EGF816)
Status: Active, Not Recruiting
Drug: Nivolumab + EGF816 + Capmatinib
Phase: P2
Countries: US, Australia, France, Germany, Italy, Netherlands, Singapore, Spain, Switzerland

NIH Identifier: NCT04310007

Link: <https://clinicaltrials.gov/ct2/show/NCT04310007>

Title: Testing the Addition of the Pill Chemotherapy, Cabozantinib, to the Standard Immune Therapy Nivolumab Compared to Standard Chemotherapy for Non-small Cell Lung Cancer
Status: Recruiting
Drug: Cabozantinib + Nivolumab
Phase: P2
Countries: US

NIH ID: NCT02954991

Link: <https://clinicaltrials.gov/ct2/show/NCT02954991>

Title: Phase 2 Study of Glesatinib, Sitravatinib or Mocetinostat in Combination with Nivolumab in Non-Small Cell Lung Cancer
Status: Recruiting
Drug: Glestatinib, Sitravastinib or Mocetinostat + Nivolumab
Phase: P2
Countries: US

NIH ID: NCT03666143

Link: <https://clinicaltrials.gov/ct2/show/NCT03666143>

Title: A Phase 1b Study to Assess Sitravatinib in Combination with Tislelizumab in Patients With Advanced Solid Tumors.
Status: Recruiting
Drug: Sitravatinib + Tislelizumab
Phase: P1
Countries: Australia, China

NIH ID: NCT04323436

Link: <https://clinicaltrials.gov/ct2/show/NCT04323436>

Title: Study of Capmatinib and Spartalizumab/Placebo in Advanced NSCLC Patients with MET Exon 14 Skipping Mutations
Status: Recruiting
Drug: Capmatinib + Spartalizumab
Phase: P2
Countries: Belgium, France, Germany, Japan

NIH ID: NCT04139317

Link: <https://clinicaltrials.gov/ct2/show/NCT04139317>

Title: Safety and Efficacy of Capmatinib (INC280) Plus Pembrolizumab vs Pembrolizumab Alone in NSCLC With PD-L1 ≥ 50%
Status: Recruiting
Drug: Capmatinib + Pembrolizumab
Phase: P2
Countries: US, Australia, Belgium, Czechia, France, Germany, Hong Kong, India, Italy, Japan, Malaysia, Spain, Taiwan, Thailand

NIH Identifier: NCT01911507

Link: <https://clinicaltrials.gov/ct2/show/NCT01911507>

Title: INC280 and Erlotinib Hydrochloride in Treating Patients With Non-small Cell Lung Cancer
Status: Active, Not Recruiting
Drug: Capmatinib + Erlotinib
Phase: P1
Countries: US



EGFR + MET TRIALS

NIH Identifier: NCT03944772

Link: <https://clinicaltrials.gov/ct2/show/NCT03944772>

Title: Phase 2 Platform Study in Patients With Advanced Non-Small Lung Cancer Who Progressed on First-Line Osimertinib Therapy (ORCHARD) (ORCHARD)

Status: Recruiting

Drug: Osimertinib + Salvotinib

Phase: P2

Countries: US, Denmark, Japan, Republic of Korea, Netherlands, Norway, Spain, Sweden

NIH Identifier: NCT03940703

Link: <https://clinicaltrials.gov/ct2/show/NCT03940703>

Title: A Study of Tepotinib Plus Osimertinib in Osimertinib Relapsed Mesenchymal-epithelial Transition Factor (MET) Amplified Non-small Cell Lung Cancer (NSCLC) (INSIGHT 2) (INSIGHT 2)

Status: Recruiting

Drug: Tepotinib + Osimertinib

Phase: P2

Countries: US, Belgium, China, France, Germany, Hong Kong, Japan, Republic of Korea, Malaysia, Netherlands, Russia, Singapore, Spain, Taiwan, Thailand, Vietnam

NIH Identifier: NCT02609776

Link: <https://clinicaltrials.gov/ct2/show/NCT02609776>

Title: Study of JNJ-61186372, a Human Bispecific EGFR and cMet Antibody, in Participants with Advanced Non-Small Cell Lung Cancer (CHRYSALIS)

Status: Recruiting

Drug: JNJ-61186372

Phase: P1

Countries: US, Australia, Canada, China, France, Italy, Japan, Republic of Korea, Spain, Taiwan, United Kingdom

NIH Identifier: NCT03778229

Link: <https://www.clinicaltrials.gov/ct2/show/NCT03778229>

Title: Osimertinib Plus Savolitinib in EGFRm+/MET+ NSCLC Following Prior Osimertinib (SAVANNAH)

Status: Recruiting

Drug: Osimertinib + Salvotinib

Phase: P2

Countries: US, Brazil, Canada, Chile, Denmark, France, India, Israel, Italy, Japan, Republic of Korea, Spain, Taiwan, Vietnam

NIH ID: NCT04606771

Link: <https://clinicaltrials.gov/ct2/show/NCT04606771>

Title: A Study Comparing Savolitinib Plus Osimertinib vs Savolitinib Plus Placebo in Patients with EGFRm+ and MET Amplified Advanced NSCLC (CoC)

Status: Recruiting

Drug: Osimertinib + Savolitinib

Phase: P2

Countries: US, Argentina, Brazil, Chile, India, Republic of Korea, Taiwan, Thailand, Vietnam

ANTIBODY-ADC TRIALS

NIH Identifier: NCT03539536

Link: <https://clinicaltrials.gov/ct2/show/NCT03539536>

Title: Study of Telisotuzumab Vedotin (ABBV-399) in Subjects with Previously Treated c-Met+ Non-Small Cell Lung Cancer

Status: Recruiting

Drug: ABBV-399

Phase: P2

Countries: US, Australia, Belgium, Canada, China, France, Germany, Greece, Hungary, Ireland, Israel, Italy, Japan, Republic of Korea, Romania, Russia, Spain, Taiwan, Turkey, United Kingdom

NIH Identifier: NCT04077099

Link: <https://clinicaltrials.gov/ct2/show/NCT04077099>

Title: REGN5093 in Patients With MET-Altered Advanced Non-Small Cell Lung Cancer

Status: Recruiting

Drug: REGN5093

Phase: P1, P2

Countries: US, Republic of Korea

NIH Identifier: NCT02648724

Link: <https://www.clinicaltrials.gov/ct2/show/NCT02648724>

Title: Sym015 (Anti-MET) in Patients With Advanced Solid Tumor Malignancies

Status: Active, Not Recruiting

Drug: Sym015

Phase: P1, P2

Countries: US, Denmark, Hong Kong, Republic of Korea, Spain, Taiwan



The MET Crusader newsletter is written for the benefit of MET patients, caregivers, clinicians and researchers. It contains an outlined summary of MET related abstracts, posters and articles. The outline summaries improves readability while providing key metrics. The summaries are not intended to replace the abstracts, posters or articles. Where possible, links are provided to the source materials. Where links are not possible, a reference is made to help locate the source documents. If you need help in finding a document contact us.

Where possible, the outlined summaries contain the NIH ID that links to the actual clinical trial. This helps our community in the evaluation of clinical trials. The drug(s) under trial is also provided.

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