SWOG CANCER RESEARCH NETWORK

Distribution Date: January 1, 2019
E-mailed Date: December 21, 2018

TO: ALL NATIONAL CLINICAL TRIALS NETWORK (NCTN) MEMBERS

FROM: Mariah Norman, Protocol Coordinator (E-mail: mnorman@swog.org)

RE: **S1400**, "A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (LUNG-MAP)". Study Chairs: V. Papadimitrakopoulou, F.R. Hirsch, P.C. Mack, R.S. Herbst, L.W. Schwartz, and D.R. Gandara.

STATUS CHANGE

Study Chair: Vassiliki A. Papadimitrakopoulou, M.D.
Phone number: 713/792-6363
E-mail: vpapadim@mdanderson.org

IRB Review Requirements
(√) Expedited review allowed

Status Change
(√) Sub-Study Permanent Closure of **S1400K**

S1400K PERMANENT CLOSURE

The purpose of this memorandum is to alert sites that **S1400K** is permanently closed to accrual effective immediately. Revision # 24 has been released and should be processed by sites that have **S1400K** open.

S1400K: A Phase II Study of ABBV-399 (Process II) in Patients with c-MET Positive Stage IV or Recurrent Squamous Cell Lung Cancer (LUNG-MAP SUB-STUDY)

At a planned interim analysis, the study team reviewed patient data to date and did not find that every 3-week dosing of ABBV-399 was sufficiently active to continue enrolling patient to the study. **S1400K** will be permanently closed to accrual based on the results. This information is provided in the attached letters to patients and investigators.

Enclosed please find an "Investigator Letter" and a "Patient Information Letter" pertaining to the permanent closure of the **S1400K** sub-study.

We are asking you to do the following:

1. Submit the information to the IRB of record for the study. Please note, if the IRB of record is the NCI Central IRB, the SWOG Operations Office has submitted this information on your behalf.

2. Read the Investigator Letter.

3. Notify all patients currently receiving treatment as soon as possible of the information in the patient letter (including the results of the interim analysis) in the manner approved by your IRB.

This memorandum serves to notify the NCI and the SWOG Statistics and Data Management Center.

cc: PROTOCOL & INFORMATION OFFICE Susanne M. Arnold, M.D.
Saiama N. Waqar, MBBS, MSCI

INVESTIGATOR LETTER

Date: December 21, 2018

To: **S1400K** Participating Investigators

From: Vassiliki Papadimitrakopoulou, M.D. – S1400 Study Chair
Saiama N. Waqar, MBBS, MSCI – S1400K Study Chair
Susanne M. Arnold, M.D. – S1400K Study Co-Chair
Roy Herbst, M.D., Ph.D. – S1400 Study Chair
David Gandara, M.D. – S1400 Study Chair
Karen Kelly, M.D. – SWOG Lung Committee Chair

RE: Interim futility analysis of **S1400K:** "A Phase II Study of ABBV-399 (Process II) in Patients with c-MET Positive Stage IV or Recurrent Squamous Cell Lung Cancer (LUNG-MAP SUB-STUDY)"

S1400K was permanently closed to accrual on December 21, 2018 as the study met pre-specified futility threshold at planned interim analysis.

Patients currently receiving treatment on **S1400K** must be notified that the study team reviewed patient data to date and did not find that every 3-week dosing of ABBV-399 was sufficiently active to continue enrolling patients to the study. The manner by which this notification should take place is at the discretion of the local Institutional Review Board (IRB). At a minimum, patients currently receiving the experimental therapy (ABBV-399) must be notified of the results of the interim analysis. The attached "Patient Information Letter" may be used if desired. Documentation that this information has been provided must be retained in the patient's research record on site and will be subject to verification at the time of a Quality Assurance audit.

Patients currently receiving treatment on **S1400K** may continue treatment with ABBV-399 at the discretion of the treating physician if the patient is deriving clinical benefit, agrees to continue treatment, and if their physician feels that it is in the patient's best interest to continue treatment at this time.

It is recommended that the patient be notified as soon as possible to make the determination of whether to continue treatment.

Sites are expected to continue the protocol-specified data submission requirements in Section 14.0 for all patients.

Continued follow-up and reporting of adverse events, progression and survival is important to all subsequent analyses of this trial. Therefore, we strongly encourage all investigators to continue to submit follow-up forms on this trial. We also request that any outstanding forms be completed and submitted as soon as possible.

Please direct questions to:
Eligibility/Data Submissions: **S1400**Question@crab.org
Protocol/Regulatory: mnorman@swog.org
S1400K Treatment-related/Medical: **S1400K**MedicalQuery@swog.org

Thank you for your continued participation in the **S1400** - Lung-MAP trial.

*[Patient Letter: For patients currently receiving treatment on **S1400K**]*

PATIENT INFORMATION LETTER

S1400, "A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer" Lung-MAP Protocol Study Chairs: V. Papadimitrakopoulou, F.R. Hirsch, P.C. Mack, R.S. Herbst, L.W. Schwartz, and D.R. Gandara.

Sub-study: **S1400K** Biomarker-Driven c-MET – ABBV-399

You are participating in a SWOG research study for advanced squamous cell lung cancer in patients like you who had previously progressed after receiving chemotherapy. You were enrolled on a sub-study (**S1400K**) and have been receiving treatment with ABBV-399. It was stated in your Consent Form that you would be given any new information that might affect your health and/or your willingness to continue in the study. We, the SWOG study investigators, have new information regarding the effectiveness of ABBV-399 for patients in the study. The study team reviewed the patient data to date and did not find that ABBV-399 was sufficiently active to continue enrolling patients to this study.

You are currently receiving ABBV-399, and you can continue to receive the drug if you are experiencing clinical benefit, you agree to continue treatment, and if you and your physician feel that it is in your best interest to continue the treatment. You will continue to be followed as described in your Consent Form, whether you decide to continue or discontinue study treatment. If your cancer gets worse, you should stop receiving the treatment.

Should you and your physician decide to stop the treatment, you will continue to be followed off study treatment and further treatment options will be discussed by your treating physician.

We have greatly appreciated your participation in the trial. The results from this research study will contribute to the knowledge of how best to treat patients with advanced squamous cell lung cancer. You should discuss any questions you have about this "Patient Information Letter" with your study doctor.

Thank you very much for your participation.

Sincerely,

Vassiliki Papadimitrakopoulou, M.D.
Saiama N. Waqar, MBBS, MSCI
Susanne M. Arnold, M.D.
Roy Herbst, M.D., Ph.D.
David Gandara, M.D
Karen Kelly, M.D.