2. SYNOPSIS

<table>
<tr><td>Name of Sponsor/Company:
Celgene Corporation</td><td rowspan="3">Individual Study Table Referring to Part of the Dossier
Volume:
Page:</td><td rowspan="3">(For National Authority Use Only)</td></tr>
<tr><td>Name of Finished Product:
Not applicable</td></tr>
<tr><td>Name of Active Ingredient:
Not applicable</td></tr>
<tr><td colspan="3">Title of Study: MPACT Extension Study: Multicenter, Survival Data Collection in Subjects Previously Enrolled in Protocol CA046</td></tr>
<tr><td colspan="3">Principal Investigator:
Investigators: Multicenter study, subjects at 32 sites.</td></tr>
<tr><td colspan="3">Study center(s): This multicenter study was conducted by investigators in 9 countries and subjects at a total of 32 sites: United States (US), 13 sites; Canada, 5 sites; Austria, 3 sites; Spain, 3 sites; Australia, 3 sites; France, 2 sites; Italy, 1 site; Ukraine, 1 site; and Germany, 1 site</td></tr>
<tr><td colspan="3">Publications (reference): None</td></tr>
<tr><td colspan="2">Studied period (years):
Date first patient enrolled: 30 Jan 2013
Date last patient completed: 14 Apr 2015</td><td>Phase of development: 4</td></tr>
<tr><td colspan="3">Objectives:
Primary: The primary objective of this study was to collect survival/vital status of CA046 subjects who were known to be alive at the last report of vital status for CA046 (approximate timeframe – end of March 2013).
Secondary: The secondary objectives of the study were to collect date of disease progression and subsequent anticancer therapy for pancreatic adenocarcinoma other than that already recorded for subject while enrolled in CA046.</td></tr>
<tr><td colspan="3">Methodology: This study was a multicenter, survival data collection for subjects previously enrolled in Study CA046 whose vital status was “alive” as of the last update prior to database lock of 09 May 2013 (approximate data cutoff date of the end of March, 2013) and study closure. Approximately 70 subjects who were enrolled in Study CA046, at approximately 50 investigational sites, were alive as of the last update prior to database lock of 09 May 2013 and study closure. This extension study to Study CA046 was conducted to collect follow-up survival data not included in Study CA046.
All follow-up information was recorded in the study case report form (CRF) at the time of subject enrollment and thereafter no less than quarterly, until the subject reached 3 year overall survival, was deceased, had been lost in follow-up, withdrawn consent, or study completion, whichever came first.
The End of Trial was defined as either the date of the last visit of the last subject to complete the study, or the date of receipt of the last data point from the last subject that was required for primary, secondary and/or exploratory analysis, as pre-specified in the protocol and/or the Statistical Analysis Plan,</td></tr>
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whichever was the later date.

This study was planned to end when all enrolled subjects reached 3 year survival, have died, have been lost to follow-up, or have withdrawn consent.

Number of patients (planned and analyzed): Approximately 70 subjects who were enrolled in Study CA046, at approximately 50 investigational sites, were alive as of the last update prior to database lock of 09 May 2013 and study closure. Overall, 45 (68.2%) of 66 eligible subjects enrolled in the extension study, 26 from the ABI-007/gemcitabine arm and 19 from the gemcitabine arm of Study CA046.

Diagnosis and main criteria for inclusion: Subjects must have met all of the following inclusion criteria to be eligible for enrollment into the study:

1. Must have been enrolled in Study CA046.
2. Must have been living at the time of the last survival follow-up reported in Study CA046.
3. Must have understood and been able to give informed consent (if a subject was deceased, proper legal consent [ie, next of kin, legal representative] was to be obtained prior to collection of data, where permitted).

Test product, dose and mode of administration, batch number: None

Duration of treatment: This was an observational study with no administration of investigational product (IP). This study was planned to end when all enrolled subjects reached 3 year survival, have died, have been lost to follow-up, or have withdrawn consent.

Reference therapy, dose and mode of administration, batch number: None

Criteria for evaluation:

Efficacy: The primary endpoint was the vital status as determined by overall survival information for Study CA046 subjects who were known to be alive at the last report of vital status prior to the approximate data cutoff date of the end of March 2013 for Study CA046. The number and percentage of subjects alive and deceased, and the years of survival from the time of randomization in Study CA046 to the end of this study were summarized.

The Extension Follow-up-Population is the primary population for all statistical summaries of extension follow-up data. The Extension Follow-up Population consists of all subjects who met eligibility criteria, and for whom follow-up data was provided based on subject agreement via informed consent and IRB/IEC approval or IRB/IEC approval to provide data from medical records). For summarization of the data, subjects were included in the treatment arm to which they were randomized in Study CA046.

Secondary endpoints were: 1) dates of disease progression for those subjects whose disease had not progressed as of the last assessment of disease status prior to the approximate data cutoff date of the end

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of March 2013 for Study CA046 and 2) subsequent anticancer therapies for pancreatic adenocarcinoma other than those already recorded for subjects while enrolled in Study CA046.

Safety: There was no administration of IP in this observational follow-up to Study CA046. There were no safety assessments planned and no safety analysis conducted.

Statistical methods:

This was an observational study with no administration of IP. The primary endpoint was the vital status as determined by overall survival information for Study CA046 subjects who were known to be alive at the last report of vital status prior to the approximate data cutoff date of the end of March 2013 for Study CA046. The number and percentage of subjects alive and deceased, and the years of survival from the time of randomization in Study CA046 to the end of this study were summarized.

Secondary endpoints were: 1) dates of disease progression for those subjects whose disease had not progressed as of the last assessment of disease status prior to the approximate data cutoff date of the end of March 2013 for Study CA046 and 2) subsequent anticancer therapies for pancreatic adenocarcinoma other than those already recorded for subjects while enrolled in Study CA046.

For summarization of the data, subjects were included in the treatment arm to which they were randomized in Study CA046.

SUMMARY – CONCLUSIONS

EFFICACY RESULTS:

All primary and secondary endpoint data summaries were based on the Extension Follow-up Population. This population consists of all subjects who met eligibility criteria, and for whom follow-up data was provided based on subject agreement via informed consent and Investigational Review Board (IRB)/Independent Ethics Committee (IEC) approval or IRB/IEC approval to provide data from medical records.

While the treatment arms were well balanced with regard to demographics and baseline characteristics in the base study (Study CA046), imbalances between treatment arms are evident for subjects enrolled in the extension study as these subjects are a subset of those from Study CA046. No comparison between treatment arms is intended.

Subjects in the Extension Follow-up Population were predominantly White, not Hispanic or Latino (82.2%) and nearly half (46.7%) were female. The median age of subjects was 64. The majority of subjects were of Karnofsky Performance Status (KPS) 90 to 100 and no subject had a KPS < 80.

Of the 70 subjects in Study CA046 known to be alive at study closure, 45 subjects enrolled in the extension follow-up study. Overall, 13 subjects completed the study, 31 subjects died during the study and 1 was lost to follow up.

A total of 14 (31.1%) subjects who entered the extension study were alive at their last follow-up visit and 31 (68.9%) subjects had died as of the Study CA046C data cutoff date of 16 Apr 2015. One of the 14 subjects who were alive at their last follow-up visit was lost to follow-up and did not complete the study.

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Nearly two-thirds of subjects survived ≥ 2 years in both treatment groups (61.5% in the ABI-007/gemcitabine arm and 63.2% in the gemcitabine arm) as assigned in the base study.

In the ABI-007/gemcitabine arm, 13 subjects had not yet progressed at the end of Study CA046 and 8 of these had a first documented progression in the extension study, while in the gemcitabine arm, 5 subjects had not yet progressed at the end of Study CA046 and 2 of these had a first documented progression in the extension study. Four subjects in the ABI-007/gemcitabine arm and 3 subjects in the gemcitabine arm had not yet progressed at the end of the extension study.

Approximately half the subjects in each treatment arm received a newly started anticancer chemotherapy in the extension study, the most common category was the 5-fluorouracil (5-FU)/capecitabine-based agents, received by 24.4% overall, with a similar percentage between treatment arms.

SAFETY RESULTS:

There was no administration of IP in this observational follow-up to Study CA046. There were no safety assessments planned and no safety analysis conducted.

CONCLUSION:

In this survival extension study it was observed that an additional 10 subjects had first documented disease progression and for 7 subjects the duration of disease stabilization was extended relative to the CA046 study. A total of 14 (31.1%) subjects who entered the extension study were alive at their last follow-up visit and 31 (68.9%) subjects had died as of the Study CA046C data cutoff date of 16 Apr 2015.

Date of the report: 20 Aug 2015