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SUMMARY OF RESEARCH

# Summary of Research: Adjuvant Nivolumab Plus Ipilimumab Versus Placebo for Localized Renal Cell Carcinoma After Nephrectomy (CheckMate 914): A Double-Blind, Randomized, Phase 3 Trial

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**Abstract**
This is a summary of a research article reporting Part A of the CheckMate 914 study (NCT03138512; EudraCT 2016-004502-34). Following surgery to remove renal cell carcinoma (RCC), people with a high risk of the cancer returning received nivolumab plus ipilimumab (adjuvant therapy) or placebo to see if this risk was reduced. The results of this study showed that the risk of RCC returning or death was not changed with adjuvant nivolumab plus ipilimumab treatment compared with placebo. In addition, people treated with nivolumab plus ipilimumab had more side effects compared with people treated with placebo (89% versus 57%).

## 1 Introduction

This summary of research article summarizes Part A of the CheckMate 914 study [1].

## 2 What is Renal Cell Carcinoma?

Renal cell carcinoma (RCC) is a type of cancer that begins in the lining of the nephrons in the kidney. Surgery is the standard treatment for people with early stages of RCC that is still within or next to the kidney and has not spread to elsewhere in the body. This surgery involves removing part of a kidney or kidney tumor (partial nephrectomy) or an entire kidney plus nearby tissue (radical nephrectomy). In about one-third of people who have surgery, RCC will come back within their kidneys or spread to other parts of the body.

## 3 What did Part A of this Study Look at?

In Part A of the CheckMate 914 study (NCT03138512; EudraCT 2016-004502-34) people at high risk of RCC coming back after partial or radical nephrectomy received nivolumab plus ipilimumab (adjuvant therapy) to see if it lowered the risk of RCC returning compared with the risk of disease returning in similar patients receiving placebo.

## 4 What were Researchers Investigating?

Researchers compared the median length of time people who received adjuvant nivolumab and ipilimumab survived and were free of the cancer returning after starting treatment (disease-free survival), with the median duration of disease-free survival in similar patients who received placebo after surgery. They also looked for side effects that people had with treatment.

## 5 Who Participated in Part A of this Study?

In total, 816 people from 20 countries participated: 405 people were assigned to receive treatment with nivolumab (one 240-mg dose every 2 weeks for a total of 12 doses) plus ipilimumab (one 1-mg/kg dose every 6 weeks for a total of 4 doses), and 411 people were assigned to receive placebo administered in the same way as the active treatment.

Extended author information available on the last page of the article

## 6 What did the Results of Part A of the Study Show?

The percentage of people who were living and cancer free at 24 months was 76% in the nivolumab plus ipilimumab group and 74% in the placebo group. Median disease-free survival was 50.7 months with placebo. Median disease-free survival with nivolumab plus ipilimumab could not be calculated because more than half of people assigned to this treatment were still cancer-free and living at the end of follow-up period (median follow-up was 37 months). The risk of RCC returning or death was not changed with adjuvant nivolumab plus ipilimumab treatment compared with placebo.

In people treated with nivolumab plus ipilimumab, 89% had one or more side effects compared with 57% of people treated with placebo. The most common side effects related to nivolumab plus ipilimumab treatment (occurring in ≥ 15% of people) were pruritus, fatigue, rash, diarrhea, hyperthyroidism, and hypothyroidism. Side effects related to treatment that were severe or very severe occurred in 28% of people treated with nivolumab plus ipilimumab and 2% of people treated with placebo. There were four deaths (1%) in the nivolumab plus ipilimumab-treated group and none in the placebo-treated group that were considered related to treatment.

## 7 What were the Main Conclusions?

Adjuvant therapy with nivolumab plus ipilimumab did not improve disease-free survival versus placebo in people with RCC who were at high risk of their cancer returning after partial or radical nephrectomy.

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## Declarations

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## Reference

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