Clinical Study Results

Study Name

Title of the Study:	A Randomized, Double-blind Study Evaluating the Efficacy, Safety, and Immunogenicity of ABP 798 Compared with Rituximab in Subjects with CD20 Positive B-cell Non-Hodgkin Lymphoma (NHL)
Brief Title:	Study to Assess if ABP 798 is Safe & Effective in Treating Non-Hodgkin Lymphoma Compared to Rituximab (JASMINE)
Protocol Number:	20130109
EU Trial Number	2013-005542-11
Other Identifiers	NCT02747043
Date of This Summary	27 April 2020

What does this summary cover?

This summary shows the main results from one clinical study. The results are only for this study. Other studies may find different results. Researchers and health authorities look at the results of many studies to decide which medicines work best and are safest for patients.

1. Who Sponsored This Study?

Amgen Inc.
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Amgen Inc. is the sponsor of the study and manufactured ABP 798, the investigational medicine included in the study. Amgen would like to thank everyone who participated in this study and feels it is important to share the results of this study.

2. General Information About the Clinical Trial

Where and when was the study done?

- This study took place in 20 countries.
- The study began in May 2016 and ended in June 2019.
- The study was completed as planned.

Why was the study done?

Non-Hodgkin lymphoma (NHL) is cancer that begins in the lymphocytes, which are a type of white blood cell. White blood cells are part of the body's immune system. There are many types of NHL, but they all have similar characteristics. Patients with NHL may have swollen/enlarged lymph nodes in the neck, groin, or underarms. They may also feel very tired and have stomach or chest pain, fever, and night sweats.

Common treatments for NHL include radiation therapy, chemotherapy, and antibody therapy. Antibodies are proteins made by the immune system. Antibody therapies use antibodies that are made in a lab to help fight cancer.

Rituximab (Rituxan®/MabThera®) is a type of antibody therapy that is currently approved in some countries for the treatment of NHL in adults. Rituximab may help the immune system to destroy cancer cells, and may also destroy cancer cells on its own.

Rituximab is also known as a biologic medicine, which is a medicine that contains one or more active substances that are made by or come from living organisms.

ABP 798 is another IV biologic medicine. It was created to be highly similar to rituximab. Once a new biologic product has been tested and is shown to be highly similar to a reference biologic product, it is called a "biosimilar." In clinical studies like this one, ABP 798 is called an investigational medicine, and rituximab is called the reference product.

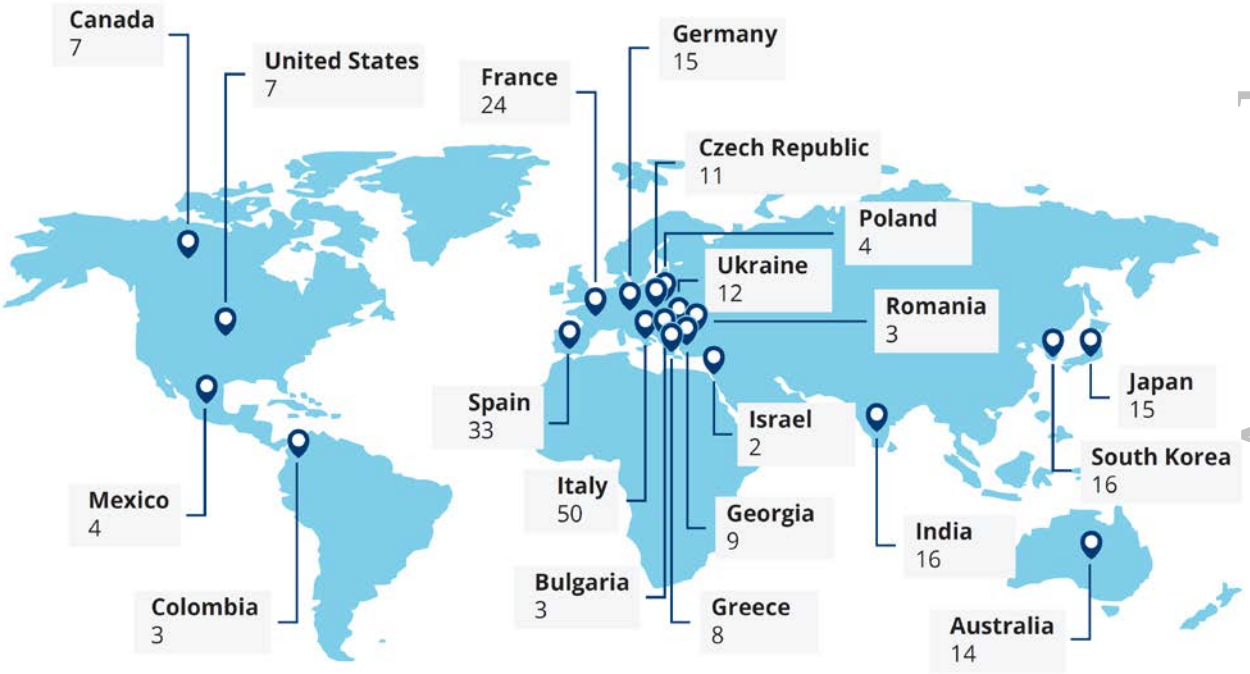
This was a phase 3 study, the late stage of the development process of medicines for humans. The main purpose of this study was to compare the effectiveness of ABP 798 with rituximab in adults with a type of NHL called CD20 Positive B-cell NHL (follicular lymphoma).

3. Who was Included in This Study?

Who took part in the study?

This study included 256 participants with follicular lymphoma. 130 participants (51%, or about 51 out of 100) were women and 126 participants (49%, or about 49 out of 100) were men. They ranged in age from 24 to 84 years. 141 participants (55%, or about 55 out of 100*)* were 60 years old or younger. 115 participants (45%, or about 45 out of 100) were older than 60 years.

This study took place at 91 study centers across 20 countries. The number of participants in each country are shown below.



Participants were examined by a study doctor and chosen to be in the study if they:

- were 18 years of age or older
- were diagnosed with follicular lymphoma that involves more than one lymph node region
- were considered to have a low tumor burden (low amount of cancer cells in the body)
- had follicular lymphoma that was considered to be mildly aggressive (tumors grow at a slower rate)

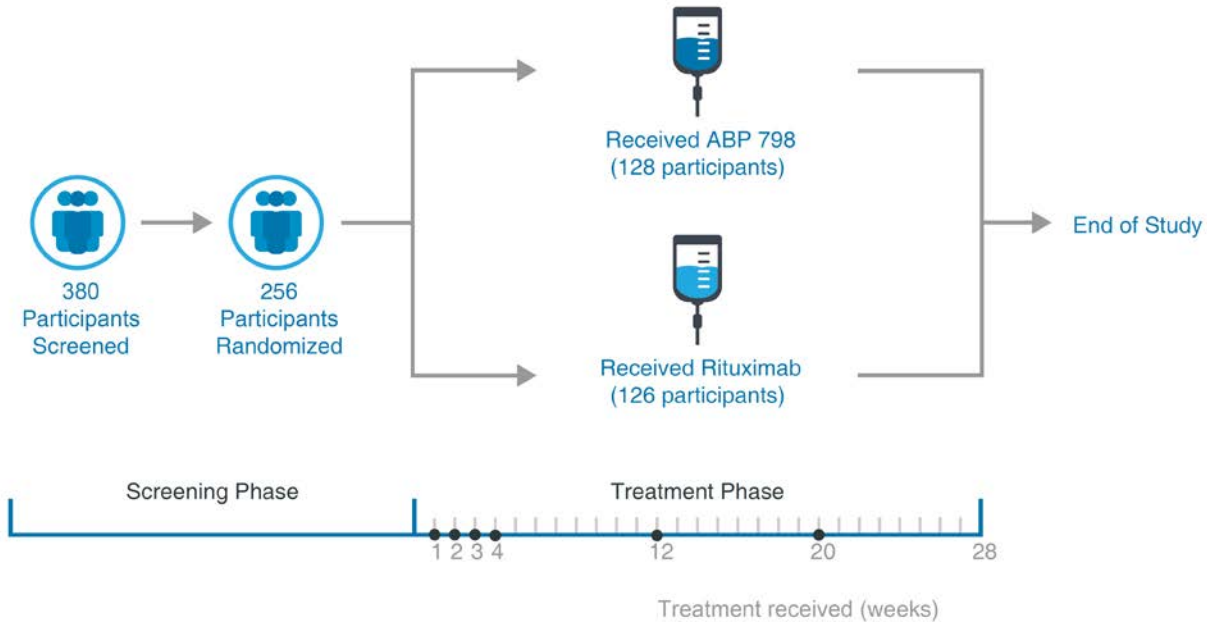
4. Which Medicines Were Studied?

In this study, ABP 798 was compared with rituximab. Participants had an equal chance of receiving either treatment.

Neither the participants nor the study doctors could choose which treatment participants were given. Participants agreed to be put into a treatment group by chance ("randomized") using an automated computer system. This is like flipping a coin or drawing numbers out of a hat.

This was a "double-blinded" study, which means that the participants and the study doctors could only find out which treatment the participant was given after the entire study was completed. This was done to make sure the study conduct and results were not influenced in any way.

ABP 798 or rituximab were given as intravenous (in the vein) infusions. The ABP 798 dose was 375 mg/m^2 (milligrams per body surface area) and the rituximab dose was 375 mg/m^2. Treatment was given once weekly for 4 weeks, and then at week 12 and week 20. Tumors were evaluated at screening, and then again at week 12 and week 28. Week 28 was considered the end of the study.



5. What Were the Side Effects?

What is an adverse reaction (sometimes called a side effect)?

A lot of research is needed to know whether a medicine causes a side effect. All medicines can cause side effects, or unwanted medical problems that may happen when you take a medicine. In a clinical study, the study doctors record all unwanted medical problems that occur during the study including side effects that they believe are possibly caused by the investigational medicine each participant is receiving. These are also called “adverse reactions.”

What side effects related to the investigational medicine were seen?

When reporting side effects in this study, the study doctor did not know which treatment a participant was receiving. A side effect was recorded as “serious” if it caused death, was life threatening, required the participant to stay in a hospital, or the study doctor thought it was clinically important enough to record as “serious”. No participant in this study died due to a side effect.

The table below shows how many participants had side effects that were considered related to treatment.

Side Effects During the Study		
	ABP 798 Group (128 participants)	**Rituximab Group (126 participants)**
How many participants had serious side effects?	2 participants (2%)	3 participants (2%)
How many participants had non-serious side effects?	59 participants (46%)	62 participants (49%)
How many participants died from side effects?	0 participants (0%)	0 participants (0%)
How many participants stopped taking the study medicine because of side effects?	3 participants (2%)	1 participant (1%)

The table below shows the serious side effects considered by the study doctor as related to treatment that occurred during the study.

Serious Side Effects During the Study		
Serious side effect	**ABP 798 Group (128 participants)**	**Rituximab Group (126 participants)**
Infection of the windpipe, airways, and lungs	1 participant (1%)	0 participants (0%)
Fever	1 participant (1%)	0 participants (0%)
Infection that can cause low blood pressure and organ failure (septic shock)	1 participant (1%)	0 participants (0%)
Inflammation of mouth and lips	1 participant (1%)	0 participants (0%)
Chills	0 participants (0%)	1 participant (1%)
Inflammation and ulcers in colon (ulcerative colitis)	0 participants (0%)	1 participant (1%)
Difficulty swallowing	0 participants (0%)	1 participant (1%)
Impotence (erectile dysfunction)	0 participants (0%)	1 participant (1%)
Headache	0 participants (0%)	1 participant (1%)
Runny nose	0 participants (0%)	1 participant (1%)

The table below shows the non-serious side effects considered by the study doctor as related to treatment that occurred in at least 5% of participants (or about 5 out of 100).

Non-serious Side Effects During the Study

Non-serious side effect	ABP 798 Group (128 participants)	Rituximab Group (126 participants)
Feeling tired	8 participants (6%)	5 participants (4%)
Irritated throat	8 participants (6%)	7 participants (6%)
Rash	7 participants (6%)	4 participants (3%)
Hives	7 participants (6%)	2 participants (2%)
Headache	6 participants (5%)	8 participants (6%)
Nausea	6 participants (5%)	9 participants (7%)
Itching	6 participants (5%)	11 participants (9%)

This section only shows the most frequently reported side effects considered by the study doctor as related to treatment. No single clinical study can give a complete picture of the benefits and risks of a medicine. Information about other side effects may be available at the websites listed at the end of this summary.

6. What Were the Overall Results of the Study?

By week 28, what percentage of participants who took ABP 798 had a response to treatment, compared to participants who took rituximab?

To answer this question, the study doctors evaluated the participants' tumors at screening, week 12, and week 28. They used physical exams and imaging tests to evaluate the tumors. The study doctors compared the results to see if participants had a response to treatment.

The study doctors found that:

- 96 out of 123 participants who took ABP 798 (78%, or about 78 out of 100) had a response to treatment.
- 87 out of 124 participants who took rituximab (70%, or about 70 out of 100) had a response to treatment.
- The difference between the 2 groups was about 8% (so, about 8% more participants who took ABP 798 had a response to treatment than participants who took rituximab).

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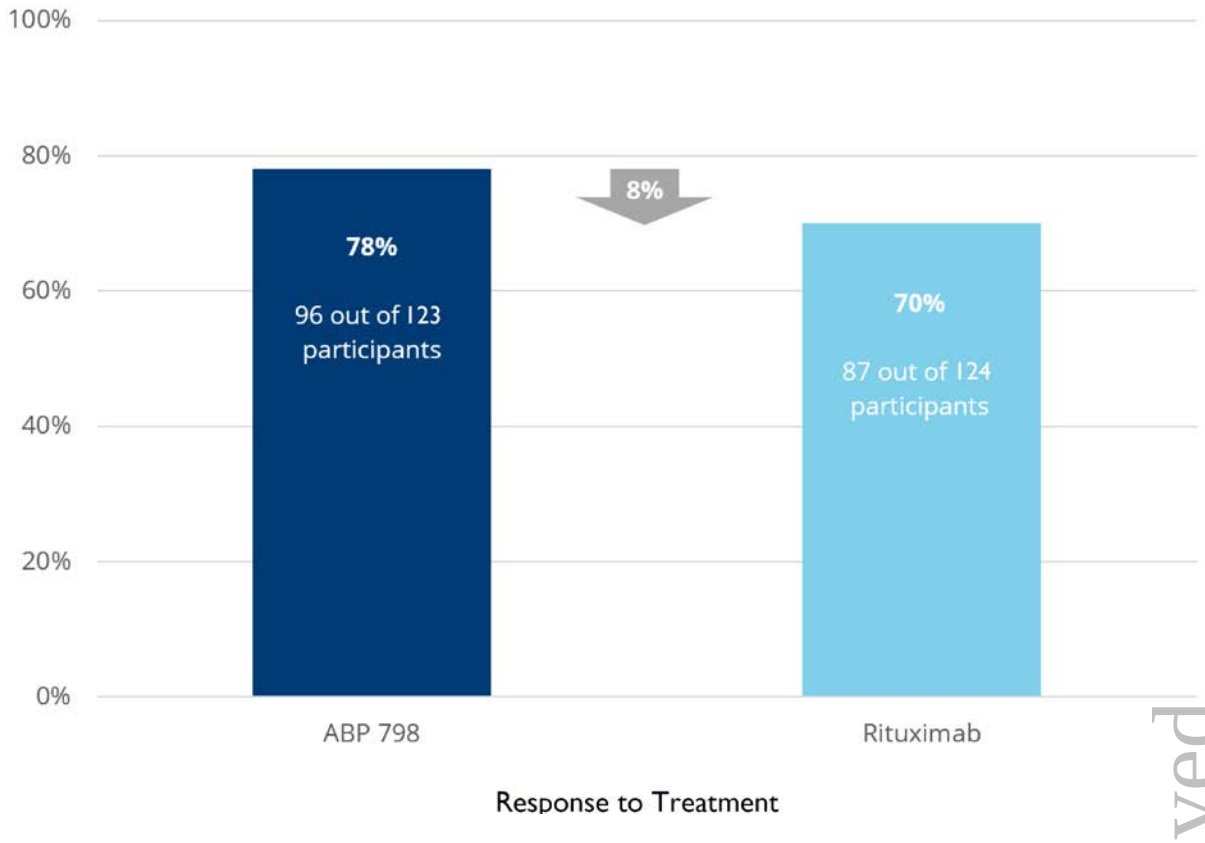

This study was completed as planned. More results may be available at the websites listed at the end of this summary.

7. How Has This Study Helped Participants and Researchers?

What is important to know about these results?

These results are only for this clinical study, which looked at a sample of 256 people with follicular lymphoma. Not all participants in the study had the same results. The results for any individual participant could have been better or worse than the results for their group. Other studies may find different results.

This research may help future participants and families by helping doctors understand more about the treatment being studied. These results are not an explanation of what a treatment can and cannot do for an individual.

8. Are There Plans for Further Studies?

If more clinical studies are done, they may be listed on public websites, such as those below. Search for study medicine name ABP 798 on the websites below.

9. Where Can I Find More Information About This Study?

Amgen has committed to make research results available to the public. This summary has been provided as part of that commitment and should not be used for any other purpose. It should not be considered to make a claim for any product or to guide treatment decisions.

To find out more about this study, check these websites:

- www.clinicaltrials.gov. Use the study identifier NCT02747043
- www.clinicaltrialsregister.eu. Use the study identifier 2013-005542-11

If you participated in the study and have questions about the study results, the doctor or staff at your study site may be able to answer them.