

# Summary of Clinical Trial Results

For Laypersons



**A study to learn how effective and safe a new medicine called ABBV-3373 is when compared to adalimumab and placebo for adult patients with moderate to severe rheumatoid arthritis**

## Overall Summary

- Rheumatoid arthritis (RA) is a disease that causes the body's immune system, which helps fight infection, to attack itself. RA targets the body's joints causing inflammation (swelling, pain, and redness).
- When the symptoms disappear for a long period of time, it is called remission. When the symptoms increase in severity, it is called a flare.
- The main goal of this study was to find out if patients' signs and symptoms of RA improved after 12 weeks of treatment with a new medicine called ABBV-3373.
- Signs and symptoms of RA were measured by using the disease activity score 28 (DAS28) and levels of C-reactive protein (CRP) in the blood. The DAS28 measures the number of tender and swollen joints, and CRP is produced by the liver in response to inflammation in the body. When used together, these measurements are called the DAS28(CRP).
- This study included two treatment parts. In Part 1, study doctors (investigators) tested a new medicine called ABBV-3373 compared to adalimumab. In Part 2, study doctors tested placebo (looks like treatment but contains no medicine) compared to adalimumab in adult patients with moderate to severe RA.
- The study took place from March 2019 to August 2020 in 4 countries and included 48 patients.
- At the start of the study, a computer program put patients into two different groups. One group was given ABBV-3373 in Part 1 followed by placebo in Part 2. The other group was given adalimumab in Part 1 and continued taking adalimumab in Part 2.
- The study showed that patients treated with ABBV-3373 had greater improvement in DAS28(CRP) compared to previously collected data on patients treated with placebo or adalimumab (called historical reference data).
- In Part 1, around 6.5% of patients treated with ABBV-3373 and 17.6% of patients treated with adalimumab had side effects.
- In Part 2, around 16.7% of patients treated with placebo and 37.5% of patients treated with adalimumab had side effects.
- The results of this study may be used by researchers to further develop this medicine.
- If you participated in this study and have questions about your individual care, contact the doctor or staff at your study site.

# 1. General information about the study

## 1.1. What was the main objective of this study?



Rheumatoid arthritis (RA) is an autoimmune disease that causes the body's immune system, which helps fight infection, to attack itself. RA targets the body's joints and causes inflammation (swelling, pain, and redness). These symptoms can disappear and return and change in severity.

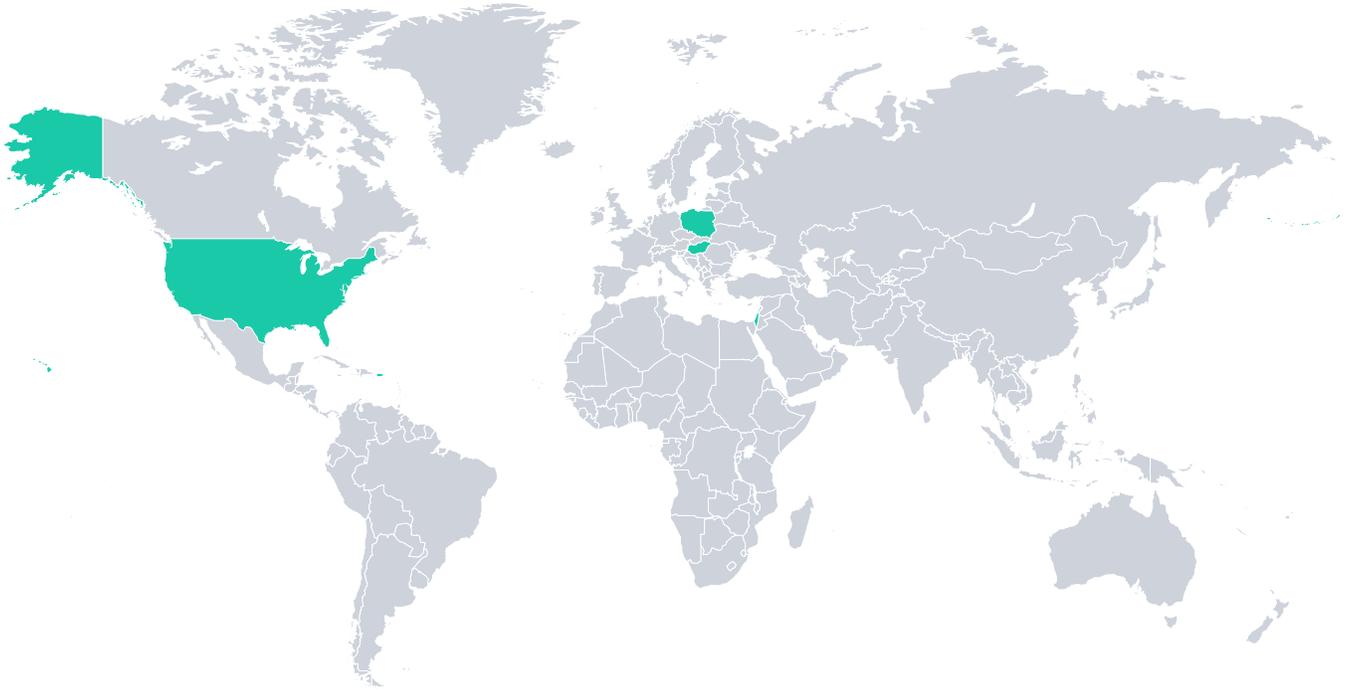
There is no cure for RA, but researchers are looking for a treatment that weakens the activity of the immune system to improve patients' symptoms. In this study, a drug called ABBV-3373 was tested in patients with RA to see if it can work on part of the immune system to help decrease inflammation. ABBV-3373 was compared to treatment with adalimumab, a drug approved to treat many autoimmune diseases, such as RA.

The main goal of this study was to see how patients' signs and symptoms of RA changed after 12 weeks of treatment based on DAS28(CRP). The DAS28 measures the number of tender and swollen joints and CRP is produced by the liver in response to inflammation in the body. This study was planned as a phase 2, double-blind, randomized study.

- **Phase 2 studies** test potential new treatments in a small number of patients with a condition or disease. In this Phase 2 study, the study doctors looked at the benefits of ABBV-3373 in patients. The study doctors also looked for any side effects patients may have had after treatment.
- **Side effects** are medical events considered by the study doctors to be at least possibly related to the study drug/treatment.
- This study was **double-blinded**, which means that neither the patients nor the study doctors knew who was given which study drug. This ensures that no study results were influenced.
- A computer program was used to randomly (by chance) put the patients into 1 of 2 groups. This process is called **randomization**, which helps make the groups similar and reduces the differences between the groups. Randomization allows the results of each treatment to be compared as accurately as possible.

## 1.2. When and where was the study done?

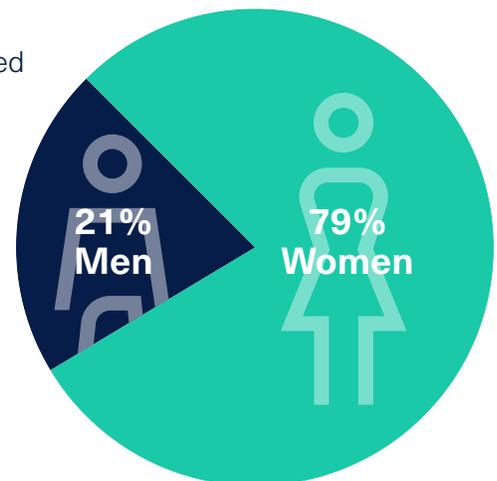
This study took place from March 2019 to August 2020 in the following countries: Hungary, Israel, Poland, and the United States (including Puerto Rico).



## 2. What patients were included in this study?

A total of 48 adult patients with active RA took part in the study. All patients completed Part 1 of the study, and 45 patients completed Part 2 of the study. All patients had RA for at least 3 months prior to joining the study and had limited improvement in their RA symptoms while taking a medicine called methotrexate.

There were more women (79%) than men (21%) in the study as RA is more common in women. Patient ages ranged from 23 to 73 years with an average age of 53 years.



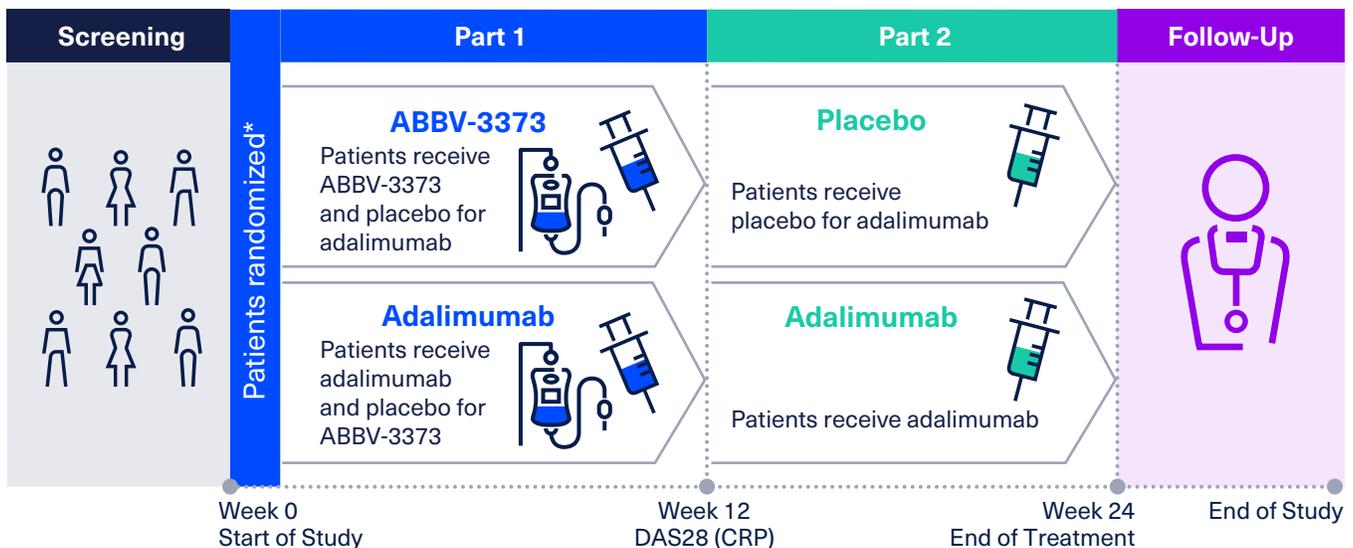
### 3. Which medicines were studied?

The medicines in this study were ABBV-3373, adalimumab, and placebo. Placebo looks like the treatment but has no medicine in it. ABBV-3373 and placebo for ABBV-3373 were given as an injection into the vein (IV) while adalimumab and placebo for adalimumab were given as an injection under the skin.

At the beginning of the study, a computer program randomized patients into two groups. Patients in the first group received ABBV-3373 and placebo for adalimumab in Part 1 followed by placebo for adalimumab in Part 2. Patients in the second group received adalimumab and placebo for ABBV-3373 in Part 1 followed by adalimumab in Part 2. During the entire study, neither the patients nor study doctors knew which drug patients were given.

After 12 weeks of treatment (end of Part 1), patients' signs and symptoms of RA were evaluated by the DAS28(CRP).

The diagram below shows how the study was organized.



## 4. What were the side effects?

A side effect is serious if it leads to death, is life-threatening, puts a patient in the hospital, keeps a patient in the hospital for a long time, or causes a disability that lasts a long time.

Side effects are unwanted medical events that were considered by the study doctor to be at least possibly related to study drug.

In Part 1, 1 patient (3.2% of patients) treated with ABBV-3373 and no patient treated with adalimumab had serious side effects. In Part 2, no patient had serious side effects.

In Part 1, 1 patient (3.2% of patients) treated with ABBV-3373 and 1 patient (5.9% of patients) treated with adalimumab stopped taking the study drug because of side effects. In Part 2, no patient stopped taking the study drug because of side effects.

No patient died during the study.

The table below shows information about the serious side effects patients had in the study and side effects patients had that led to the patient stopping study drug.

	PART 1		PART 2	
	ABBV-3373 (31 Patients)	Adalimumab (17 Patients)	Placebo (30 Patients)	Adalimumab (16 Patients)
Number of patients with serious side effects	1 (3.2% of patients)	0 (0.0% of patients)	0 (0.0% of patients)	0 (0.0% of patients)
<b>Serious Side Effects</b>				
• Anaphylactic shock	1 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Number of patients who stopped taking study drug because of side effects	1 (3.2%)	1 (5.9%)	0 (0.0%)	0 (0.0%)
Reasons for stopping	Anaphylactic shock (a severe allergic reaction that decreases blood pressure and makes it difficult to breathe)	Type 1 hypersensitivity (a sudden reaction in the body which may cause a rash, wheezing, difficulty breathing, or other symptoms)	–	–

In Part 1, 2 patients (6.5% of patients) treated with ABBV-3373 and 3 patients (17.6% of patients) treated with adalimumab had side effects. All side effects occurred in only one patient.

In Part 2, 5 patients (16.7% of patients) treated with placebo and 6 patients (37.5% of patients) treated with adalimumab had side effects. Two patients treated with placebo had upper respiratory tract infection (common infection of the nose, throat, and airways). All other side effects occurred in only one patient.

## 5. What were the overall results of the study?

The study was completed as planned. At the end of Part 1, patients' response to treatment was evaluated with the DAS28(CRP). The DAS28(CRP) scores showed that patients treated with ABBV-3373 in this study had greater improvement in their signs and symptoms of RA after 12 weeks of treatment compared to previously collected data on patients treated with placebo or adalimumab in other RA studies with similar patients (called historical reference data).

## 6. How has the study helped patients and researchers?

The study found that ABBV-3373 improves DAS28(CRP) levels in patients with active RA. Findings from this study may be used in other studies to learn more about whether patients are helped by ABBV-3373.

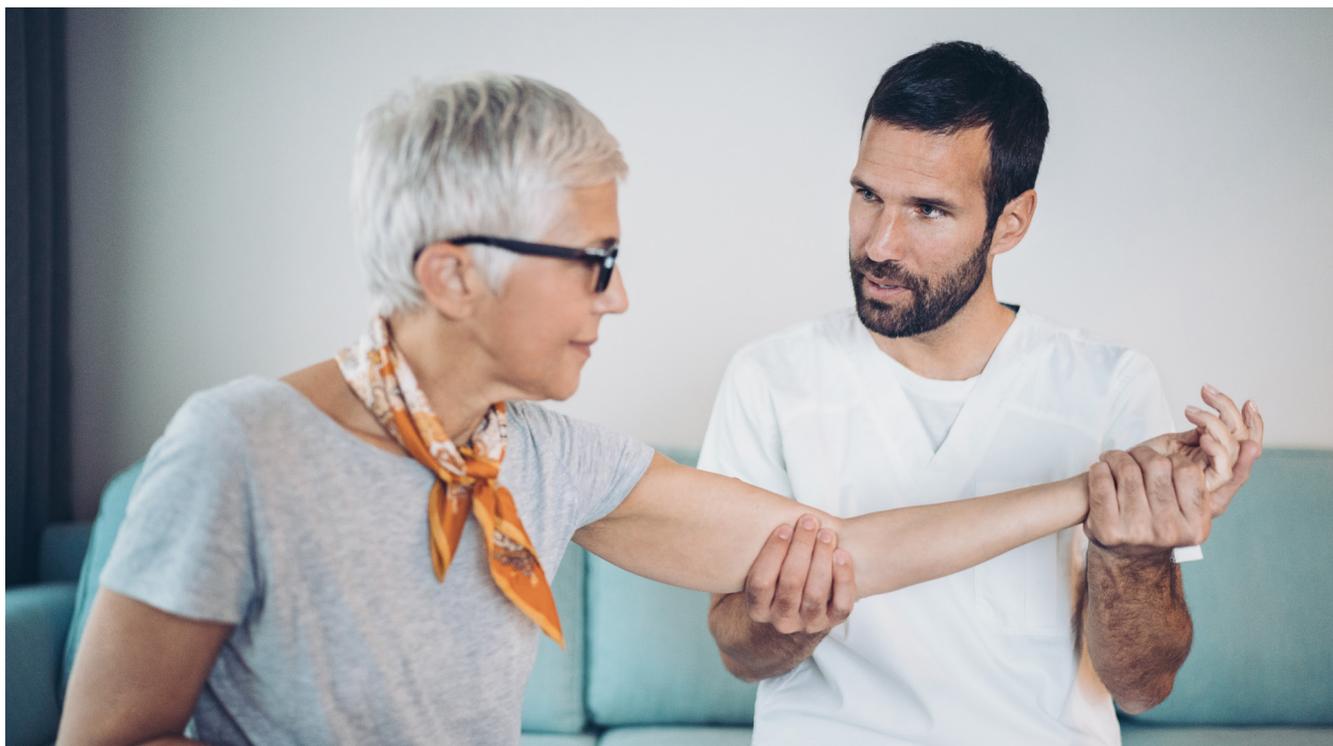
This summary only shows the results from this study, which may be different from the results of other studies.

## 7. Are there any plans for future studies?

There are currently no planned studies of ABBV-3373. There may be future studies of other study drugs in patients with RA.

## 8. Who sponsored this study?

This study was sponsored by AbbVie. This summary was reviewed for readability by a patient advocacy group.





## 9. Where can I find out more information about this study?

Title of Study	A Randomized, Double-Blind, Double-Dummy, Active Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of ABBV-3373 in Subjects With Moderate to Severe Rheumatoid Arthritis
Protocol Number	M16-560
Clinicaltrials.gov	NCT03823391 <a href="https://clinicaltrials.gov/ct2/show/NCT03823391?term=m16-560&amp;draw=2&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT03823391?term=m16-560&amp;draw=2&amp;rank=1</a>
EudraCT	2018-003053-21 <a href="https://www.clinicaltrialsregister.eu/ctr-search/search?query=2018-003053-21">https://www.clinicaltrialsregister.eu/ctr-search/search?query=2018-003053-21</a>
Study Sponsor	AbbVie, Inc. Phone: +1 800-633-9110 Email: <a href="mailto:abbvieclinicaltrials@abbvie.com">abbvieclinicaltrials@abbvie.com</a>

## Thank You

AbbVie wants to thank all the participants for their time and effort that went into making this study possible.

Clinical study participants help advance science!

