**COMMUNIQUE DE PRESSE**

April 18, 2024

# Phase 3 SELECT-GCA Study of Upadacitinib (RINVOQ®) Showed Positive Results in Patients With Giant Cell Arteritis

- *Results from the Phase 3 SELECT-GCA study showed 46 percent of patients with giant cell arteritis (GCA) who were treated with upadacitinib (RINVOQ®; 15 mg) with a 26-week steroid taper regimen achieved sustained remission from week 12 through week 52 compared to 29 percent of patients receiving placebo with a 52-week steroid taper regimen*[1]
- *The safety profile in GCA was generally consistent with that in approved indications, and no new safety signals were identified*[1]
- *The clinical program reflects AbbVie's history of developing new treatment options for patients with immune-mediated diseases, where there remains significant unmet medical need*

NORTH CHICAGO, Ill., April 18, 2024 /PRNewswire/ -- AbbVie (NYSE: ABBV) today announced positive top-line results from SELECT-GCA, a Phase 3, multicenter, randomized, double-blind, placebo-controlled study, showing upadacitinib (RINVOQ®; 15 mg, once daily) in combination with a 26-week steroid taper regimen achieved its primary endpoint of sustained remission[a] from week 12 through week 52 in adults with giant cell arteritis (GCA). In this study, 46 percent of patients receiving upadacitinib 15 mg in combination with a 26-week steroid taper regimen achieved sustained remission compared to 29 percent of patients receiving placebo in combination with a 52-week steroid taper regimen (p=0.0019).[1]

"Many people living with GCA continue to suffer from the potentially debilitating symptoms of this disease, with limited treatment options available to them," said Kori Wallace, M.D., Ph.D., vice president, global head of immunology clinical development, AbbVie. "These results demonstrate our relentless commitment to improving the lives of people living with immune-mediated diseases by developing new treatments where significant medical needs still exist."

GCA is an autoimmune disease that causes inflammation of the temporal and other cranial arteries, the aorta, and other large and medium arteries. GCA generally impacts elderly patients older than 50 years, most commonly between the ages of 70 and 80 years. Women have the highest risk of developing this disease, which can cause headache, jaw pain and changes in or loss of vision, including sudden and permanent loss of vision.[2]

Key secondary endpoints were also met, including a higher percentage of patients receiving upadacitinib 15 mg in combination with a 26-week steroid taper regimen achieved sustained complete remission[b] from week 12 through week 52 compared to patients receiving placebo in combination with a 52-week steroid taper regimen (37 percent versus 16 percent; p<0.0001).[1] A lower percentage of patients experienced at least one disease flare through week 52 in the upadacitinib 15 mg group versus the placebo group (34 percent versus 56 percent; p=0.0014).[1] The study results also showed that upadacitinib 7.5 mg did not meet the primary or any of the secondary endpoints.[1]

"I am encouraged by these results, which add to the body of evidence supporting the efficacy and safety profile of upadacitinib for the treatment of rheumatic diseases," said Daniel Blockmans, M.D., Ph.D., Department of General Internal Medicine, University Hospitals Gasthuisberg, Belgium, professor of medicine, KU Leuven, Belgium, and lead investigator of the SELECT-GCA trial. "Based on these results, upadacitinib has the potential to be the first oral treatment option for patients with GCA, a disease with inflammation of the large arteries that primarily impacts older people and has only one approved treatment to date[3] commonly used with steroids."

During the 52-week, placebo-controlled period, the safety profile of upadacitinib 15 mg was generally consistent with that observed in approved indications.[1] Upadacitinib 15 mg was generally

well tolerated, with no new safety signals identified in this GCA population.[1] Discontinuations due to adverse events occurred in 15 percent of patients in the upadacitinib 15 mg group and 21 percent of patients in the placebo group.[1] In this study, the proportion of patients who experienced a serious adverse event was similar (23 percent in the upadacitinib 15 mg group and 21 percent in the placebo group).[1] Serious infections occurred in 6 percent of the upadacitinib 15 mg group and 11 percent of the placebo group.[1] Overall, the proportions of patients with incidence of malignancy excluding non-melanoma skin cancer and adjudicated venous thromboembolic events (VTEs) were balanced across both the upadacitinib 15 mg (2 percent and 3 percent, respectively) and placebo (2 percent and 4 percent, respectively) treatment groups.[1] There were no adjudicated major adverse cardiac events (MACE) in the upadacitinib 15 mg group compared to two events in the placebo group.[1] Four treatment-emergent deaths were reported, two in the placebo group and two in the upadacitinib 15 mg group.[1] Of the two treatment-emergent deaths in the upadacitinib 15 mg group, one was attributed to COVID-19, and the other was adjudicated as an unexplained cause.[1]

Full results across all treatment groups from the SELECT-GCA study will be presented at a future medical meeting. Use of upadacitinib in GCA is not approved and its safety and efficacy have not been evaluated by regulatory authorities.

[a] *Sustained remission is defined as having an absence of GCA signs and symptoms from week 12 through week 52 and adherence to the protocol-defined steroid taper over the course of the study term.*

[b] *Sustained complete remission is defined as having an absence of GCA signs and symptoms from week 12 through week 52, adherence to the protocol-defined steroid taper, and normalization of both erythrocyte sedimentation rate (ESR) and high sensitivity C-reactive protein (hsCRP) from week 12 through week 52.*

## About SELECT-GCA

SELECT-GCA (M16-852) was a Phase 3, multicenter, randomized, double-blind placebo-controlled study designed to evaluate the safety and efficacy of upadacitinib in 428 patients with GCA. The study consists of two periods. The first period, which is reported in this release, evaluated the efficacy of upadacitinib in combination with a 26-week corticosteroid taper regimen compared to placebo in combination with a 52-week corticosteroid taper regimen. In addition, the study assessed the safety and tolerability of upadacitinib in these patients. The second period will evaluate the safety and efficacy of continuing versus withdrawing upadacitinib in maintaining remission in participants who achieved sustained remission in the first period.[1] For more information regarding this study, please visit ClinicalTrials.gov (Identifier NCT03725202).

## About Giant Cell Arteritis

Giant cell arteritis (GCA), also known as temporal arteritis, is an autoimmune disease of medium and large arteries, characterized by granulomatous inflammation of the three-layered vessel wall, which affects temporal and other cranial arteries as well as the aorta and other large arteries.[2,4] GCA can cause headache, jaw pain, and changes in or loss of vision, including sudden and permanent loss of vision.[2] It is the most common vasculitis affecting adults in western countries.[2] Caucasian women over the age of 50 – most commonly between the ages of 70 and 80 years – have the highest risk of developing giant cell arteritis. Although women are more likely than men to develop GCA, research suggests that men are more likely to have ocular manifestations with their disease.[5]

## About Upadacitinib (RINVOQ®)

Discovered and developed by AbbVie scientists, RINVOQ is a JAK inhibitor that is being studied in several immune-mediated inflammatory diseases.[6,7] Based on enzymatic and cellular assays, RINVOQ demonstrated greater inhibitory potency for JAK-1 vs JAK-2, JAK-3, and TYK-2.[6] The relevance of inhibition of specific JAK enzymes to therapeutic effectiveness and safety is not currently known. Upadacitinib (RINVOQ) is being studied in Phase 3 clinical trials for alopecia areata, giant cell arteritis, hidradenitis suppurativa, Takayasu arteritis, systemic lupus erythematosus, and vitiligo.[8-13]

**RINVOQ (upadacitinib) U.S. Uses and Important Safety Information**[6]

**RINVOQ is a prescription medicine used to treat:**

- **Adults with moderate to severe rheumatoid arthritis (RA)** when 1 or more medicines called tumor necrosis factor (TNF) blockers have been used, and did not work well or could not be tolerated.
- **Adults with active psoriatic arthritis (PsA)** when 1 or more medicines called TNF blockers have been used, and did not work well or could not be tolerated.
- **Adults with active ankylosing spondylitis (AS)** when 1 or more medicines called TNF blockers have been used, and did not work well or could not be tolerated.
- **Adults with active non-radiographic axial spondyloarthritis (nr-axSpA)** with objective signs of inflammation when a TNF blocker medicine has been used, and did not work well or could not be tolerated.
- **Adults with moderate to severe ulcerative colitis (UC)** when 1 or more medicines called TNF blockers have been used, and did not work well or could not be tolerated.
- **Adults with moderate to severe Crohn's disease (CD)** when 1 or more medicines called TNF blockers have been used, and did not work well or could not be tolerated.

It is not known if RINVOQ is safe and effective in children with juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, ulcerative colitis, or Crohn's disease.

- **Adults and children 12 years of age and older with moderate to severe eczema (atopic dermatitis [AD])** that did not respond to previous treatment and their eczema is not well controlled with other pills or injections, including biologic medicines, or the use of other pills or injections is not recommended.

RINVOQ is safe and effective in children 12 years of age and older weighing at least 88 pounds (40 kg) with atopic dermatitis.

It is not known if RINVOQ is safe and effective in children under 12 years of age with atopic dermatitis.

**IMPORTANT SAFETY INFORMATION**

**What is the most important information I should know about RINVOQ?**

**RINVOQ may cause serious side effects, including:**

- **Serious infections.** RINVOQ can lower your ability to fight infections. Serious infections have happened while taking RINVOQ, including tuberculosis (TB) and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections. Your healthcare provider (HCP) should test you for TB before starting RINVOQ and check you closely for signs and symptoms of TB during treatment with RINVOQ. You should not start taking RINVOQ if you have any kind of infection unless your HCP tells you it is okay. If you get a serious infection, your HCP may stop your treatment until your infection is controlled. You may be at higher risk of developing shingles (herpes zoster).
- **Increased risk of death in people 50 years and older who have at least 1 heart disease (cardiovascular) risk factor.**
- **Cancer and immune system problems.** RINVOQ may increase your risk of certain cancers. Lymphoma and other cancers, including skin cancers, can happen. Current or past smokers are at higher risk of certain cancers, including lymphoma and lung cancer. Follow your HCP's advice about having your skin checked for skin cancer during treatment with RINVOQ. Limit the amount of time you spend in sunlight. Wear protective clothing when you are in the sun and use sunscreen.

- **Increased risk of major cardiovascular (CV) events, such as heart attack, stroke, or death, in people 50 years and older who have at least 1 heart disease (CV) risk factor, especially if you are a current or past smoker.**
- **Blood clots.** Blood clots in the veins of the legs or lungs and arteries can happen with RINVOQ. This may be life-threatening and cause death. Blood clots in the veins of the legs and lungs have happened more often in people who are 50 years and older and with at least 1 heart disease (CV) risk factor.
- **Allergic reactions.** Symptoms such as rash (hives), trouble breathing, feeling faint or dizzy, or swelling of your lips, tongue, or throat, that may mean you are having an allergic reaction have been seen in people taking RINVOQ. Some of these reactions were serious. If any of these symptoms occur during treatment with RINVOQ, stop taking RINVOQ and get emergency medical help right away.
- **Tears in the stomach or intestines**. This happens most often in people who take nonsteroidal anti-inflammatory drugs (NSAIDs) or corticosteroids. Get medical help right away if you get stomach-area pain, fever, chills, nausea, or vomiting.
- **Changes in certain laboratory tests.** Your HCP should do blood tests before you start taking RINVOQ and while you take it. Your HCP may stop your RINVOQ treatment for a period of time if needed because of changes in these blood test results.

**Do not take RINVOQ if you are allergic to upadacitinib or any of the ingredients in RINVOQ.** See the Medication Guide or Consumer Brief Summary for a complete list of ingredients.

**What should I tell my HCP BEFORE starting RINVOQ?**

Tell your HCP if you:

- Are being treated for an infection, have an infection that won't go away or keeps coming back, or have symptoms of an infection, such as:

– Fever, sweating, or chills
– Shortness of breath
– Warm, red, or painful skin or sores on your body
– Muscle aches
– Feeling tired
– Blood in phlegm
– Diarrhea or stomach pain
– Cough
– Weight loss
– Burning when urinating or urinating more often than normal

- Have TB or have been in close contact with someone with TB.
- Are a current or past smoker.
- Have had a heart attack, other heart problems, or stroke.
- Have or have had any type of cancer, hepatitis B or C, shingles (herpes zoster), blood clots in the veins of your legs or lungs, diverticulitis (inflammation in parts of the large intestine), or ulcers in your stomach or intestines.
- Have other medical conditions, including liver problems, low blood cell counts, diabetes, chronic lung disease, HIV, or a weak immune system.
- Live, have lived, or have traveled to parts of the country, such as the Ohio and Mississippi River valleys and the Southwest, that increase your risk of getting certain kinds of fungal infections. If you are unsure if you've been to these types of areas, ask your HCP.
- Have recently received or are scheduled to receive a vaccine. People who take RINVOQ should not receive live vaccines.
- Are pregnant or plan to become pregnant. Based on animal studies, RINVOQ may harm your unborn baby. Your HCP will check whether or not you are pregnant before you start RINVOQ. You should use effective birth control (contraception) to avoid becoming pregnant during treatment with RINVOQ and for 4 weeks after your last dose.

- There is a pregnancy surveillance program for RINVOQ. The purpose of the program is to collect information about the health of you and your baby. If you become pregnant while taking RINVOQ, you are encouraged to report the pregnancy by calling 1-800-633-9110.
- Are breastfeeding or plan to breastfeed. RINVOQ may pass into your breast milk. Do not breastfeed during treatment with RINVOQ and for 6 days after your last dose.

**Tell your HCP about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. RINVOQ and other medicines may affect each other, causing side effects.

**Especially tell your HCP if you take:**

- Medicines for fungal or bacterial infections
- Rifampicin or phenytoin
- Medicines that affect your immune system

If you are not sure if you are taking any of these medicines, ask your HCP or pharmacist.

**What should I avoid while taking RINVOQ?**

Avoid food or drink containing grapefruit during treatment with RINVOQ as it may increase the risk of side effects.

**What should I do or tell my HCP AFTER starting RINVOQ?**

- Tell your HCP right away if you have any symptoms of an infection. RINVOQ can make you more likely to get infections or make any infections you have worse.
- Get emergency help right away if you have any symptoms of a heart attack or stroke while taking RINVOQ, including:
    - Discomfort in the center of your chest that lasts for more than a few minutes or that goes away and comes back
    - Severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
    - Pain or discomfort in your arms, back, neck, jaw, or stomach
    - Shortness of breath with or without chest discomfort
    - Breaking out in a cold sweat
    - Nausea or vomiting
    - Feeling lightheaded
    - Weakness in one part or on one side of your body
    - Slurred speech
- Tell your HCP right away if you have any signs or symptoms of blood clots during treatment with RINVOQ, including:

– Swelling
– Pain or tenderness in one or both legs
– Sudden unexplained chest or upper back pain
– Shortness of breath or difficulty breathing

- Tell your HCP right away if you have a fever or stomach-area pain that does not go away, and a change in your bowel habits.

**What are other possible side effects of RINVOQ?**

Common side effects include upper respiratory tract infections (common cold, sinus infections), shingles (herpes zoster), herpes simplex virus infections (including cold sores), bronchitis, nausea, cough, fever, acne, headache, increased blood levels of creatine phosphokinase, allergic reactions, inflammation of hair follicles, stomach-area (abdominal) pain, increased weight, flu, tiredness, lower number of certain types of white blood cells (neutropenia, lymphopenia, leukopenia), muscle

pain, flu-like illness, rash, increased blood cholesterol levels, increased liver enzyme levels, pneumonia, low number of red blood cells (anemia), and infection of the stomach and intestine (gastroenteritis).

A separation or tear to the lining of the back part of the eye (retinal detachment) has happened in people with atopic dermatitis treated with RINVOQ. Call your HCP right away if you have any sudden changes in your vision during treatment with RINVOQ.

Some people taking RINVOQ may see medicine residue (a whole tablet or tablet pieces) in their stool. If this happens, call your healthcare provider.

These are not all the possible side effects of RINVOQ.

**How should I take RINVOQ?**

RINVOQ is taken once a day with or without food. Do not split, crush, or chew the tablet. Take RINVOQ exactly as your HCP tells you to use it. RINVOQ is available in 15 mg, 30 mg, and 45 mg extended-release tablets.

**This is the most important information to know about RINVOQ. For more information, talk to your HCP.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.**

**If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit AbbVie.com/myAbbVieAssist to learn more.**

**Globally, prescribing information varies; refer to the individual country product label for complete information.**

**About AbbVie in Rheumatology**

For more than 20 years, AbbVie has been dedicated to improving care for people living with rheumatic diseases. Anchored by a longstanding commitment to discovering and delivering transformative therapies, we pursue cutting-edge science that improves our understanding of promising new pathways and targets, ultimately helping more people living with rheumatic diseases reach their treatment goals.

**About AbbVie**

AbbVie's mission is to discover and deliver innovative medicines and solutions that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas – immunology, oncology, neuroscience, and eye care – and products and services in our Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.com. Follow @abbvie on LinkedIn, Facebook, Instagram, X (formerly Twitter), and YouTube.

**Forward-Looking Statements**

*Some statements in this news release are, or may be considered, forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions and uses of future or conditional verbs, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those expressed or implied in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," of AbbVie's 2023 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission, as updated by its subsequent Quarterly Reports on Form 10-Q. AbbVie*

*undertakes no obligation, and specifically declines, to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.*


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For further information: Media: Lindsay Cangemi, lindsay.cangemi@abbvie.com; Investors: Liz Shea, liz.shea@abbvie.com