From: <rep's email address>
To: <recipient's email address>
Subject: Watch the final video in AbbVie's 3-part Mucosal Healing series!

WATCH NOW: How can you help deliver mucosal healing on and below the surface for your moderately to severely active patients with UC?

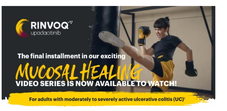
How can you help deliver mucosal healing for your patients with moderately to severely active UC?

Watch Dr. Walter Reinisch discuss the RINVOQ® (upadacitinib) UC Phase 3 clinical studies

Learn more about RINVOQ® (upadacitinib) in moderately to severely active UC

Learn more about a new treatment option for adults with moderately to severely active UC

All-mucosal option



	Dr.	
Dear	Mr.	
Hello,	Ms.	
Greetings,	Mrs.	Last Name
Hi,	Prof.	First Name
		First Name Last Name ,

How did RINVOQ affect different histologic-endoscopic mucosal healing endpoints in adult patients with moderately to severely active UC?

RINVOQ® (upadacitinib) is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.[1]

You may have already seen our previous videos as part of our exciting Mucosal Healing 3-part series. In video one Professor Subrata Ghosh introduced the concept of mucosal healing and its value as a treatment target in UC.

In our second video, Dr. Remo Panaccione discussed the rates of mucosal healing and endoscopic remission achieved with RINVOQ during its three Phase 3 clinical studies.

In our third and final video of our series, join Dr. Walter Reinisch while he provides insight into histological scoring using the Geboes scale, as well as discussing key ranked endoscopic and histologic composite endpoints of RINVOQ's clinical studies: mucosal healing (ESS of 0 or 1 without friability + Geboes ≤3.1) and deep mucosal healing (ESS of 0 + Geboes <2), the criteria of which was more stringent compared with previous studies.[1,2]

Come and see what this information could mean for your adult patients with moderately to severely active UC!

<FRAGMENT AREA>

If you have any questions or would like to go into further detail about the efficacy and safety of RINVOQ in UC, please select an option below:

Visit AbbVie Pro | Request Rep Visit | Request Samples

Sincerely,
Thanks!
See you soon,
Take care,
Best wishes,

<Rep Nickname>
<Rep Phone Number>
<Rep Email>

U-ACHIEVE Induction (UC-1) and U-ACCOMPLISH (UC-2) were replicate induction studies, both of which were multicenter, double-blind, placebo-controlled clinical studies. In UC-1 and UC-2, 988 patients (473 and 515 patients, respectively) were randomized to RINVOQ 45 mg QD or placebo for 8 weeks with a 2:1 treatment allocation ratio and included in the efficacy analysis. All enrolled patients had moderately to severely active UC defined as adapted Mayo score (aMs) of 5 to 9 with an ESS of 2 or 3 and demonstrated prior treatment failure including inadequate response, loss of response, or intolerance to prior conventional and/or biologic treatment. Primary endpoints of both studies were clinical remission per aMs at Week 8. Ranked secondary endpoints at Week 8 included clinical response per aMs, mucosal healing, histologic-endoscopic mucosal healing, and deep mucosal healing. U-ACHIEVE Maintenance (UC-3) was a multicenter, double-blind, placebo-controlled clinical study with 451 patients who achieved clinical response per aMs (decrease ≥2 points and ≥30% from baseline and a decrease in RBS ≥1 from baseline or an absolute RBS ≤1) with 8-week RINVOQ 45 mg QD induction treatment. Patients were rerandomized 1:1:1 to receive either RINVOQ 15 mg QD, 30 mg QD, or placebo. The primary endpoint was clinical remission per aMs at Week 52. Ranked secondary endpoints at Week 52 included maintenance of clinical response, corticosteroid-free clinical remission, mucosal healing, histologic-endoscopic mucosal healing, and deep mucosal healing.[1,2]

Indication[1]

RINVOQ® (upadacitinib) is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.[1]

[Affiliate to match language in local label]

Summary of safety profile[1]

[Affiliate to update with local safety based on local label]

Contraindications
RINVOQ is contraindicated in patients hypersensitive to the active substance or to any of the excipients, in patients with active tuberculosis (TB) or active serious infections, in patients with severe hepatic impairment, and during pregnancy.

Special warnings and precautions for use
Immunosuppressive medicinal products
Use in combination with other potent immunosuppressants is not recommended.

Serious infections
Serious and sometimes fatal infections have been reported in patients receiving upadacitinib. The most frequent serious infections reported included pneumonia and cellulitis. Cases of bacterial meningitis have been reported. Among opportunistic infections, TB, multidermatomal herpes zoster, oral/esophageal candidiasis, and cryptococcosis have been reported with upadacitinib. As there is a higher incidence of infections in patients ≥65 years of age, caution should be used when treating this population.

Viral reactivation
Viral reactivation, including cases of herpes zoster, was reported in clinical studies. The risk of herpes zoster appears to be higher in Japanese patients treated with upadacitinib.

Vaccinations
The use of live, attenuated vaccines during or immediately prior to therapy is not recommended. It is recommended that patients be brought up to date with all immunizations, including prophylactic zoster vaccinations, prior to initiating upadacitinib, in agreement with current immunization guidelines.

Malignancy
The risk of malignancies, including lymphoma is increased in patients with rheumatoid arthritis (RA). Malignancies, including nonmelanoma skin cancer (NMSC), have been reported in patients treated with upadacitinib. Consider the risks and benefits of upadacitinib treatment prior to initiating therapy in patients with a known malignancy other than a successfully treated NMSC or when considering continuing upadacitinib therapy in patients who develop a malignancy.

Hematological abnormalities
Treatment should not be initiated, or should be temporarily interrupted, in patients with hematological abnormalities observed during routine patient management.

Diverticulitis
Upadacitinib should be used with caution in patients with diverticular disease and especially in patients chronically treated with concomitant medications associated with an increased risk of diverticulitis.

Cardiovascular risk
RA patients have an increased risk for cardiovascular disorders. Patients treated with upadacitinib should have risk factors (e.g., hypertension, hyperlipidemia) managed as part of usual standard of care.

Lipids
Upadacitinib treatment was associated with dose-dependent increases in lipid parameters, including total cholesterol, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol.

Hepatic transaminase elevations
Treatment with upadacitinib was associated with an increased incidence of liver enzyme elevation compared to placebo

Venous thromboembolisms
Events of deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving JAK inhibitors, including upadacitinib. Upadacitinib should be used with caution in patients at high risk for DVT/PE.

Adverse reactions
The most commonly reported adverse reactions in rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis clinical trials (≥2% of patients in at least one of the indications) with upadacitinib 15 mg were upper respiratory tract infections, blood creatine phosphokinase (CPK) increased, alanine transaminase (ALT) increased, bronchitis, nausea, cough, aspartate transaminase (AST) increased, and hypercholesterolemia.

The most commonly reported adverse reactions in atopic dermatitis trials (≥2% of patients) with upadacitinib 15 mg or 30 mg were upper respiratory tract infection, acne, herpes simplex, headache, CPK increased, cough, folliculitis, abdominal pain, nausea, neutropenia, pyrexia, and influenza.

The most common serious adverse reactions were serious infections.

The safety profile of upadacitinib with long term treatment was generally similar to the safety profile during the placebo-controlled period across indications.

Overall, the safety profile observed in patients with psoriatic arthritis or active ankylosing spondylitis treated with upadacitinib 15 mg was consistent with the safety profile observed in patients with RA.

This is not a complete summary of all safety information.

Access full Summary of Product Characteristics here

aMs: adapted Mayo score; **ESS:** endoscopic subscore; **QD:** once-daily; **RBS:** rectal bleeding score; **UC:** ulcerative colitis.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events.

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ALL-RNQG-220037 June 2022

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RINVOQ upadacitinib abbvie

Eager to learn more about how RINVOQ performed on endoscopic and histologic endpoints?

WATCH VIDEO

[Affiliate to insert driver to MH video 3 location on AbbVie Pro]

Missed the first video as part of our Mucosal Healing series? Don't worry, you can catch up here!

What is mucosal healing?

WATCH VIDEO 1

[Affiliate to insert driver to MH video 1 location on AbbVie Pro]

How did RINVOQ perform on mucosal healing and endoscopic remission subscores?

WATCH VIDEO 2

[Affiliate to insert driver to MH video 2 location on AbbVie Pro]

Visit AbbVie Pro to find out more information
on how RINVOQ might benefit your adult patients
with moderately to severely active UC.

FIND OUT MORE

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