From: <rep's email address> <recipient's email address>

studies

Subject: Watch the second video in AbbVie's 3-part Mucosal Healing series!

WATCH NOW: how can you help deliver mucosal healing for your patients with moderately to severely active UC?

Is an endoscopic score of 0 the right target for your patients with moderately to severely active UC? Watch Dr. Remo Panaccione discuss the RINVOQ® (upadacitinib) UC Phase 3

Learn more about RINVOQ® (upadacitinib) in moderately to severely active UC Learn more about a new treatment option for moderately to severely active UC

RINVOQ" The second installment in our exciting upadacitinib

For adults with moderately to severely active ulcerative colitis (UC)1

Dr. Dear Mr. Hello, Ms. Last Name Greetings, First Name First Name Last Name

How did RINVOQ affect mucosal healing as measured by endoscopic subscores 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 the first video in our exciting Mucosal Healing 3-part series, where Professor Subrata Ghosh took us through what mucosal healing is, its relevance in the current treatment guidelines for ulcerative colitis, and why it is a valuable treatment target to be used in clinical practice.1

In our latest video, you'll be able to hear Dr. Remo Panaccione talk more in depth about the rates of mucosal healing achieved with RINVOQ during its three Phase 3 clinical studies at both induction and maintenance. Four mucosal healing definitions have been analyzed as ranked secondary endpoints in these studies, and the data from two of these endoscopic endpoints (mucosal healing [ESS 0 or 1 without friability] and endoscopic remission [ESS 0]) with RINVOQ vs placebo (assessed at Induction Week 8 and Maintenance Week 52) will be discussed. 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, endoscopic remission, 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, mucosal healing, endoscopic remission, histologic-endoscopic mucosal healing, and deep mucosal healing. 1.2

Indication¹

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 profile¹

EU Important Safety Information about RINVOQ® (upadacitinib)

[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.

identification of new safety information. Healthcare professionals are asked to report any suspected adverse events.

▼This medicinal product is subject to additional monitoring. This will allow quick

References: 1. RINVOQ [Summary of Product Characteristics]. AbbVie Deutschland GmbH & Co. KG. [DRAFT]. 2. Danese S, Vermeire S, Zhou W, et al. Upadacitinib as induction and maintenance therapy for moderately to severely active ulcerative colitis: results from three phase 3, multicentre, double-blind, randomised trials. Lancet. Published online May 26, 2022. doi:10.1016/S0140-6736(22)00581-5



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Learn more about RINVOQ® (upadacitinib) in moderately to severely active UC Learn more about a new treatment option for moderately to severely active UC RINVOQ The second installment in our exciting /IDEO SERIES IS NOW AVAILABLE TO WATCH! For adults with moderately to severely active ulcerative colitis (UC) Dr. Dear Mr. Hello. Ms. Greetings, Mrs. Prof. Hi, **Last Name** First Name First Name Last Name How did RINVOQ affect mucosal healing as measured by endoscopic subscores 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 the first video in our exciting Mucosal Healing 3-part series, where Professor Subrata Ghosh took us through what mucosal healing is, its relevance in the current treatment guidelines for ulcerative colitis, and why it is a valuable treatment target to be used in clinical practice.1 In our latest video, you'll be able to hear Dr. Remo Panaccione talk more in depth about the rates of mucosal healing achieved with RINVOQ during its three Phase 3 clinical studies at both induction and maintenance. 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Access full Summary of Product

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information. Healthcare professionals

References: 1. RINVOQ [Summary of

Deutschland GmbH & Co. KG. [DRAFT].

2. Danese S, Vermeire S, Zhou W, et al.

maintenance therapy for moderately to severely active ulcerative colitis: results

from three phase 3, multicentre, double-

abbvie

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Upadacitinib as induction and

blind, randomised trials. Lancet.

Published online May 26, 2022.

RINVOQ

upadacitinib

doi:10.1016/S0140-6736(22)00581-5

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ALL-RNQG-220036 June 2022

aMs: adapted Mayo score; ESS:

RBS: rectal bleeding score; UC:

quick identification of new safety

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with upadacitinib 15 mg was

observed in patients with RA.

all safety information.

Characteristics here

ulcerative colitis.

adverse events.

indications.

reactions were serious infections.

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series!

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patients with moderately to

severely active UC?

AbbVie's 3-part Mucosal Healing

WATCH NOW: how can you help deliver mucosal healing for your

Is an endoscopic score of 0 the right target for your patients with moderately to severely active UC?

Watch Dr. Remo Panaccione

(upadacitinib) UC Phase 3 studies

discuss the RINVOQ®

Excited to find out more about RINVOQ and its rates of mucosal healing in its clinical program?

WATCH VIDEO 2

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

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

WATCH VIDEO 1

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

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