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Results From SKYRIZI™ (risankizumab) Phase 3 Study in Moderate to Severe Plaque Psoriasis Published in The Lancet

- *In the IMMvent study, 72 percent and 84 percent of patients treated with SKYRIZI™ (risankizumab) achieved PASI 90 and sPGA 0/1, respectively, at week 16 [i]*

Maidenhead, UK, 24 July 2019 — AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, today announced the publication of positive results from the pivotal Phase 3 IMMvent clinical study in *The Lancet*. The study evaluates the safety and efficacy of SKYRIZI™ (risankizumab) up to 44 weeks compared to adalimumab in adult patients with moderate to severe chronic plaque psoriasis.[1] Risankizumab met the co-primary endpoints of at least a 90 percent improvement in the Psoriasis Area and Severity Index (PASI 90) and a static Physician Global Assessment (sPGA) score of clear or almost clear (0/1) versus adalimumab at weeks 16 and 44 ($p<0.0001$).[1]

"By achieving high levels of skin clearance through to week 44, risankizumab demonstrated the ability to make a positive, lasting impact on all the signs and symptoms of psoriasis," said Dr Anthony Bewley, Consultant Dermatologist, Barts Health NHS Trust, London. "I am really pleased to see that my patients stand to benefit from the positive IMMvent study results about risankizumab that appeared recently in *The Lancet*."

At week 16, 72 percent of patients receiving risankizumab (n=301) at the label dose achieved PASI 90 compared to 47 percent of patients treated with adalimumab (n=304) at the label dose.[1] 84 percent of risankizumab-treated patients achieved a sPGA score of clear or almost clear (0/1) compared to 60 percent of patients receiving adalimumab.[1] Additionally, 40 percent and 41 percent of patients treated with risankizumab achieved complete skin

clearance (defined as PASI 100 and sPGA 0, respectively) at week 16 compared to 23 percent of patients treated with adalimumab (for both measures of skin clearance).[1]

In the second phase (week 16 to week 44) of IMMvent, patients receiving adalimumab who achieved a response of at least PASI 50 but less than PASI 90 at week 16 (intermediate responders*) were re-randomised to either switch to risankizumab (n=53) or continue adalimumab (n=56).[1] Of these patients, those re-randomised to risankizumab saw significantly greater response rates.[1] 66 percent achieved PASI 90 at week 44 when switched to risankizumab, compared to 21 percent of patients who continued on adalimumab ($p<0.001$).[1] Additionally, 40 percent of patients who switched to risankizumab achieved complete skin clearance (PASI 100 or sPGA 0) at week 44 compared to 7 percent of patients who continued treatment with adalimumab (for both measures of skin clearance). All the patients who switched to risankizumab at week 16 started at the initial label dose schedule.[1]

Risankizumab is part of a collaboration between Boehringer Ingelheim and AbbVie, with AbbVie leading development and commercialisation globally.

“Publication of these positive results in *The Lancet* marks another important milestone demonstrating the potential of risankizumab to be an important treatment option that is now available in our dermatology portfolio,” said Dr Alice Butler, UK Medical Director, AbbVie.

IMMvent Efficacy Results [1] **				
	Week 16 (all patients)	**Week 44 (intermediate responders group)***		
Risankizumab (n=301)	**Adalimumab (n=304)**	**Adalimumab/ risankizumab (n=53)**	**Adalimumab/ adalimumab (n=56)**	
PASI 90	72%	47%	66%	21 %
sPGA 0/1	84%	60%	74%	34 %

PASI 100	40%	23%	40%	7%
sPGA 0	41%	23%	40%	7%

*Intermediate responders are defined as patients who achieved at least PASI 50 but less than PASI 90 at week 16.**All primary and ranked secondary endpoints achieved p-values of <0.0001.

The study also showed patients treated with risankizumab self-reported an improved quality of life. At week 16, significantly more patients treated with risankizumab achieved a Dermatology Life Quality Index (DLQI) score of 0 or 1, indicating psoriasis no longer had an impact on their health-related life quality, compared to adalimumab.[ii] Risankizumab-treated patients maintained reported outcomes at week 44.[2]

In the study, no new safety findings were observed in patients receiving continuous risankizumab or in those switched from adalimumab to risankizumab.[1] There was no increase in adverse events in patients re-randomised from adalimumab to risankizumab.[1] Serious adverse events occurred in 3 percent of patients treated with both risankizumab and adalimumab.[1] The most frequently reported adverse events for both risankizumab and adalimumab were viral upper respiratory tract infection, upper respiratory tract infection and headache.[1]

About the Phase 3 IMMvent study[1]

The IMMvent study is a Phase 3 randomised, double-blind, active-controlled study designed to evaluate the safety and efficacy of risankizumab compared to adalimumab in adult patients with moderate to severe chronic plaque psoriasis. Risankizumab is a humanised immunoglobulin G1 (IgG1) monoclonal antibody designed to selectively inhibit IL-23 by binding to its p19 subunit and is approved in the EU for adults living with moderate to severe psoriasis who are candidates for systemic treatment.[3]

In the first phase, patients were randomised 1:1 to either risankizumab (150 mg) or adalimumab (80 mg initial dose followed by 40 mg one week later and every other week thereafter) as a subcutaneous injection. Patients originally randomised to risankizumab received it throughout the study given at baseline, week 4, week 16, week 28 and week 40. Those originally randomised to adalimumab followed a treatment course based on week 16 response: those with less than PASI 50 at week 16 switched to risankizumab; those with PASI 90 continued adalimumab; and those with a PASI 50 but less than PASI 90 response were re-randomised to switch to risankizumab or

continue adalimumab. Any patient re-randomised from adalimumab to risankizumab at week 16 received it at week 16, week 20, week 32 and week 44. Results from the study showed risankizumab achieved all primary and ranked secondary endpoints.More information on this trial can be found at www.clinicaltrials.gov (NCT02694523).

About risankizumab in the European Union[3]

Risankizumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Important EU Safety Information[iii]

Risankizumab is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients. Risankizumab may increase the risk of infection. In patients with a chronic infection, a history of recurrent infection, or known risk factors for infection, risankizumab should be used with caution. Treatment with risankizumab should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated.

Prior to initiating treatment with risankizumab, patients should be evaluated for tuberculosis (TB) infection. Patients receiving risankizumab should be monitored for signs and symptoms of active TB. Anti-TB therapy should be considered prior to initiating risankizumab in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed.

Prior to initiating therapy with risankizumab, completion of all appropriate immunisations should be considered according to current immunisation guidelines. If a patient has received live vaccination (viral or bacterial), it is recommended to wait at least 4 weeks prior to starting treatment with risankizumab. Patients treated with risankizumab should not receive live vaccines during treatment and for at least 21 weeks after treatment.

The most frequently reported adverse reactions were upper respiratory infections, which occurred in 13 percent of patients. Commonly (greater than or equal to 1/100 to less than 1/10) reported adverse reactions included tinea infections, headache, pruritus, fatigue and injection site reactions.

About adalimumab in the European Union[iv]

Adalimumab is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy.

Important EU Safety Information[4]

Adalimumab is contraindicated in patients with active tuberculosis or other severe infections such as sepsis, and opportunistic infections and in patients with moderate to severe heart failure (NYHA class III/IV). It is also contraindicated in patients hypersensitive to the active substance or to any of the excipients; serious allergic reactions including anaphylaxis have been reported. The use of adalimumab increases the risk of developing serious infections, including hepatitis B reactivation, which may, in rare cases, be life-threatening. Rare cases of lymphoma and leukaemia have been reported in patients treated with adalimumab. On rare occasions, a severe type of cancer called hepatosplenic T-cell lymphoma has been observed and often results in death. A risk for the development of malignancies in patients treated with TNF-antagonists cannot be excluded. Rare cases of pancytopenia, aplastic anaemia, demyelinating disease, lupus, lupus-related conditions and Stevens-Johnson syndrome have been reported in patients treated with adalimumab. The most frequently reported adverse events across all indications included respiratory infections, injection site reactions, headache and musculoskeletal pain.

This is not a complete summary of all safety information. See SKYRIZI (risankizumab) and HUMIRA (adalimumab) full summary of product characteristics (SmPC) at https://www.medicines.org.uk/emc. Globally, prescribing information varies; refer to the individual country product label for complete information.

[i] Reich, K., Efficacy and Safety of Risankizumab Compared with Adalimumab in Patients with Moderate-to-Severe Plaque Psoriasis: Results from a Randomized, Double-blind, Active-comparator, Controlled Phase 3 Trial (IMMvent). The Lancet. 2019.

[ii] Crowley, J., et al. ePoster #P1947. 27th European Academy of Dermatology

and Venereology (EADV) Congress. September 2018.

[iii] SKYRIZI [Summary of Product Characteristics]. AbbVie Ltd. Available at: https://www.ema.europa.eu.

[iv] HUMIRA [Summary of Product Characteristics]. AbbVie Ltd.; Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000481/WC500050870.pdf. Last updated October 5, 2017. Accessed June, 2019.

About AbbVie

AbbVie is a global, research-driven biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. In more than 75 countries, AbbVie employees are working every day to advance health solutions for people around the world. For more information about AbbVie, please visit us at www.abbvie.co.uk. Follow us on twitter: @abbvieuk.

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