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HEALTH TECHNOLOGY BRIEFING
AUGUST 2020

BMS-986165 for moderate to severe plaque psoriasis

NIHRIO ID	24241	**NICE ID**	10072
Developer/Company	Bristol-Myers Squibb Pharmaceuticals Ltd	**UKPS ID**	649027

Licensing and market availability plans	Currently in phase III clinical trials.

SUMMARY

BMS-986165 is in clinical development for moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Psoriasis is an inflammatory disease whereby the body's immune system becomes over-active resulting in the life cycle of skin cells to drastically speed up. This causes a build-up of red, scaly, flaky and itchy patches of skin to appear that often involve the knees, elbows, scalp and lower back. Plaque psoriasis is thought to be caused by a combination of genetic susceptibility and triggers such as stress, smoking and hormonal changes. Treatment is determined by the area of skin affected and the severity of the plaque psoriasis and may include a combination of topical, phototherapy and systemic (oral or injected) therapies.

BMS-986165 is administered orally as tablets. It selectively blocks the tyrosine kinase 2 (TYK2) enzyme. TYK2 is an intracellular signalling enzyme that is involved in the development of plaque psoriasis. Many patients with moderate to severe psoriasis struggle with insufficient disease control. BMS-986165 is more selective than other kinase inhibitors currently available so it can target the pathways involved in psoriasis more effectively with potentially reduced toxicity and side effects. If licensed, BMS-986165 will offer a new treatment option for patients with moderate to severe plaque psoriasis.

PROPOSED INDICATION

Indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy.[1-3]

TECHNOLOGY

DESCRIPTION

BMS-986165 is an orally available, TYK2 inhibitor that binds to the pseudo-kinase domain on TYK2.[4,5] TYK2 is an intracellular signalling enzyme that activates a signal transducer and activator of transcription (STAT) dependent gene expression and functional responses of interleukin-12, interleukin-23 and type I interferon receptors. These pathways are involved in the pathologic processes associated with immune-mediated disorders, including psoriasis.[4-6]

BMS-986165 is currently in clinical development for the treatment of moderate-to-severe plaque psoriasis in phase III studies. In the phase III clinical trial (IM011046, EudraCT-2018-001925-24) participants received a 6mg dose of BMS-986165, a 30mg dose of apremilast or placebo administered orally daily throughout up to a 52 week treatment period.[7] In the phase III clinical trial (IM011046, EudraCT-2018-001926-25) participants received a 6mg dose of BMS-986165, a 30mg dose of apremilast or placebo administered orally daily throughout a 16 week treatment period.[8] In both studies, patients completing 52 weeks of treatment will be offered the opportunity to roll over to a separate long-term extension study (≥2 years) and be treated with open-label BMS-986165 6 mg once daily.[7,8]

INNOVATION AND/OR ADVANTAGES

Currently, patients with moderate to severe psoriasis have a limited number of oral therapy treatment options and many struggle with insufficient disease control so there is a need for more effective therapies.[9] BMS-986165 is functionally more selective than other kinase inhibitors enabling this drug to target specific cytokine pathways namely interleukin-12, interleukin-23 and type I interferons which are implicated in psoriasis.[4]

Furthermore, in the phase II clinical trials of BMS-986165, there was an absence of neutropenia, dyslipidaemia and elevations in liver enzyme and serum creatinine level which have been observed in other clinical trials for plaque psoriasis involving JAK inhibitors that target similar cytokines.[5]

DEVELOPMENT STATUS AND/OR REGULATORY DESIGNATIONS

BMS-986165 does not currently have Marketing Authorisation in the EU/UK for any indication.

BMS-986165 is also currently in phase II clinical development for the treatment of ulcerative colitis, systemic lupus erythematosus and Crohn's disease.[10]

PATIENT GROUP

DISEASE BACKGROUND

Psoriasis is an inflammatory skin disease that causes rapid and abnormal build-up of skin cells that typically follows a relapsing and remitting course.[11,12] Psoriasis can occur at any age but most often develops in adults under 35 years old. The first peak age of onset occurs between 16-22 years and there is a second peak age of onset between 57-60 years.[13] Plaque psoriasis (psoriasis vulgaris) is the most common type of psoriasis accounting for around 90% of psoriasis cases.[14,12] It is characterised by well-delineated red, scaly plaques that vary in extent from a few patches to generalised involvement but most commonly involves the knees, elbows, scalp and lower back.[11,12]

Psoriasis can be graded as mild, moderate or severe according to the body surface area affected or by using indices such as the Psoriasis Area Severity Index (PASI), which takes into accounts the size of the area covered with psoriasis as well as the redness, thickness and scaling. Severe psoriasis is defined by a total PASI score of >10.[15]

Psoriasis is an immune disease whereby activated T-cells migrate to the skin and release cytokines that cause the skin cells to reproduce and mature at an accelerated rate.[16] A normal skin cell goes through several phases of development before maturing and falling off (shedding) from the body's surface as dead skin cells in 28 to 30 days.[17,18] However, skin affected by psoriasis takes only three to four days to mature and move to the surface. This results in dead skin cells not being shed quickly enough to keep up with the new skin cells being produced so the cells pile up and form thick, flaky lesions resulting in plaque psoriasis.[17,18] Dilated blood vessels in psoriasis affected areas create warmth and redness in the skin lesions.[19]

What first triggers the inflammatory process that results in plaque psoriasis is not fully understood but is thought to be a complex mix of genetic susceptibility and environmental triggers. Psoriasis runs in families and if both parents are affected by psoriasis there is a 65% lifetime risk of the child being affected by psoriasis.[20] Triggers for psoriasis are things such as skin injury, excessive alcohol consumption, smoking, stress, hormonal changes during puberty or menopause and certain medicines such as ibuprofen or ACE inhibitors.[21] Psoriasis is associated with several comorbidities such as, cardiovascular disease, depression, lymphoma, diabetes, and psoriatic arthritis in 20-40% of cases.[22,23]

Moderate-to-severe psoriasis is associated with significant comorbidity and has been shown to severely impair quality of life. Studies have shown that impairment of health-related quality of life (QoL) in patients with psoriasis is comparable with that due to hypertension, diabetes, cancer and depression. Disease symptoms such as itching and pain can interfere with ordinary day-to day activities such as washing and sleeping and psoriasis on the hands and feet can hinder activities associated with daily living.[23]

CLINICAL NEED AND BURDEN OF DISEASE

Psoriasis affects around 2% of the people in the UK, affecting men and women equally.[14] Around 90% of these cases are thought to be plaque psoriasis and 20% of those will be categorised as moderate-to-severe psoriasis.[11,24] Based on the population estimate for UK in mid-2018 this would result in the estimated number of patients diagnosed with moderate-to-severe plaque psoriasis in the UK to be 239,168 patients.[25]

In 2018-19 there were 1,517 finished consultant episodes (FCE) and 1,421 admissions for psoriasis vulgaris (ICD-10 code L40.0) which resulted in 803 day cases 2,834 FCE bed days.[26]

PATIENT TREATMENT PATHWAY

TREATMENT PATHWAY

Psoriasis management aims to keep the condition under control and referring the patient to a skin specialist (dermatologist) if the symptoms become particularly severe. Which treatment option is provided usually depends on the severity of the disease and the area of skin affected.[13,27]

Treatment falls into three categories.[28]

- Topical treatments such as creams, ointments or lotions.
- Phototherapy treatment where ultraviolet light is delivered in a controlled manner to the affected skin.
- Systemic treatments whereby a medication works throughout the entire body.[29]

Health providers will usually start with a mild treatment such as topical creams and then progress to stronger treatments or a combination of treatments if necessary.[27]

CURRENT TREATMENT OPTIONS

There are currently 2 main types of systemic treatment. Biological treatments (mainly injections) which are usually used for severe psoriasis that has not responded well to other treatments and non-biological treatments (mainly orally by tablets or capsules).[27,30,31]

Non-biological medications include:

- methotrexate
- ciclosporin
- acitretin
- apremilast
- dimethyl fumarate.

Biological treatments include:

- etanercept
- adalimumab
- infliximab (for very severe psoriasis)
- ustekinumab
- guselkumab
- brodalumab
- certolizumab pegol
- risankizumab
- tidrakizumab
- secukinumab

PLACE OF TECHNOLOGY

If licensed, BMS-986165 will offer an additional treatment option for patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy.

CLINICAL TRIAL INFORMATION

Trial	**POETYK-PSO-1**, NCT03624127, EudraCT 2018-001926-25; A Multi-Center, Randomized, Double-Blind, Placebo- and Active Comparator-Controlled Phase 3 Study to Evaluate the Efficacy and Safety of BMS-986165 in Subjects With Moderate-to-Severe Plaque Psoriasis **Phase III** – Ongoing **Estimated Primary Completion Date:** 19 July 2020	NCT04036435, EudraCT 2019-000612-29; An Open-Label, Multi-Center Extension Study to Characterize the Long-Term Safety and Efficacy of BMS-986165 in Subjects With Moderate-to-Severe Plaque Psoriasis **Phase III Extension** – ongoing **Estimated Primary Completion Date:** January 5, 2024
Trial design	Randomized, quadruple masking, double-blind, placebo controlled, active comparator controlled, parallel group assignment	Open-label, single group assignment, extension
Population	N=600; adults aged 18 years and older; plaque psoriasis for at least 6 months; moderate to severe disease; candidate for phototherapy or systemic therapy	N=1680; prior completion of the protocol-required treatment period in an applicable study of BMS-986165 in moderate-to-severe psoriasis
Intervention(s)	BMS-986165 (oral administration)	BMS-986165 (oral administration)
Comparator(s)	Placebo (oral administration) or the active comparator apremilast (oral administration)	No comparator
Outcome(s)	Primary outcome measures: • Percentage of participants who achieve static Physician's Global Assessment (sPGA) score of 0 to 1 response [Time Frame: Baseline to Week 16] • Percentage of participants who achieve PASI 75 (75% reduction in Psoriasis Area and Severity Index) [Time Frame: Baseline to Week 16] See trial record for full list of other outcomes	Primary outcome measure: • Incidence of Adverse Events and Serious Adverse Events [Time Frame: 96 weeks] See trial record for full list of other outcomes
Results (efficacy)	-	-
Results (safety)	-	-

Trial	**POETYK-PSO-2,** NCT03611751, EudraCT 2018-001925-24; A Multi-Center, Randomized, Double-Blind, Placebo-

	and Active Comparator-Controlled Phase 3 Study With Randomized Withdrawal and Retreatment to Evaluate the Efficacy and safety of BMS-986165 in Subjects With Moderate-to-Severe Plaque Psoriasis **Phase III** – ongoing **Locations:** 10 EU countries (incl UK), United States, Canada and other countries **Estimated Primary Completion Date:** 10 December 2020
Trial design	Randomized, parallel assignment, double-blind, quadruple masking, placebo and active comparator controlled
Population	N=1000; plaque psoriasis for at least 6 months; moderate to severe disease; candidate for phototherapy or systemic therapy
Intervention(s)	6mg BMS-986165 (oral administration) once daily
Comparator(s)	Placebo (oral administration) or the active comparator apremilast (oral administration)
Outcome(s)	Primary outcome measures: • Percentage of participants who achieve static Physician's Global Assessment (sPGA) score of 0 to 1 response [Time Frame: Baseline to Week 16] • Percentage of participants who achieve PASI 75 (75% reduction in Psoriasis Area and Severity Index) [Time Frame: Baseline to Week 16] See trial record for full list of other outcomes
Results (efficacy)	-
Results (safety)	-

Trial	NCT02931838; A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Phase 2 Study to Evaluate the Clinical Efficacy and Safety of BMS-986165 in Subjects With Moderate to Severe Psoriasis **Phase II** – Completed **Locations:** 3 EU countries (not incl UK), United States, Canada and other countries. **Estimated Primary Completion Date:** 16 November 2017
Trial design	Randomized, parallel-assignment, double-blind, placebo-controlled
Population	N=270; aged 18 to 70 years; diagnosis of plaque psoriasis for 6 months
Intervention(s)	5 experimental arms:[5] • 3mg BMS-986165 twice daily (oral administration) • 3mg BMS-986165 daily (oral administration) • 3mg BMS-986165 every other day (oral administration) • 6mg BMS-986165 daily (oral administration) • 12mg BMS-986165 daily (oral administration)
Comparator(s)	Placebo (oral administration)
Outcome(s)	Primary outcome measures:

	• Proportion of subjects reaching a 75% reduction in Psoriasis Area and Severity Index (PASI-75) [Time Frame: Day 1 to Day 85] • Number of adverse events [Time Frame: Day 1 to 115] See trial record for full list of outcome measures
Results (efficacy)	At week 12, the percentages of patients in whom at least PASI 75 was achieved were 7% with placebo, 9% with 3 mg of BMS-986165 every other day (P=0.49 vs. placebo), 39% with 3 mg daily (P<0.001 vs. placebo), 69% with 3 mg twice daily (P<0.001 vs. placebo), 67% with 6 mg twice daily (P<0.001 vs. placebo), and 75% with 12 mg daily (P<0.001 vs. placebo).[5]
Results (safety)	Adverse events were reported in 51% of the patients in the placebo group and 55 to 80% in the active-drug groups, with the highest percentage in the 6mg twice daily group. Nasopharyngitis, headache, diarrhoea, nausea, and upper respiratory tract infection were the most common adverse events. Adverse events leading to discontinuation of the trial regimen occurred in 4% of the patients in the placebo group and 2 to 7% of the patients across the active-treatment groups. There was a higher occurrence of mild-to-moderate acne in the active-treatment groups than in the placebo groups, with 4 cases (9%) in the highest-dose group. Five serious adverse events were reported in four patients: two events in one patient in the placebo group (haemorrhagic anaemia and haemorrhoidal haemorrhage) and one event in one patient each in the groups receiving 3mg every other day (gastroenteritis due to rotavirus), 3mg daily (accidental eye injury), and 3mg twice daily (dizziness due to vestibular dysfunction with a history of the same).[5]

ESTIMATED COST

The cost of BMS-986165 is not yet known.

RELEVANT GUIDANCE

NICE GUIDANCE

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- NICE technology appraisal. Guselkumab for treating moderate to severe plaque psoriasis (TA521). June 2018.
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- NICE technology appraisal. Ixekizumab for treating moderate to severe plaque psoriasis (TA442). April 2017
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- NICE technology appraisal. Secukinumab for treating moderate to severe plaque psoriasis (TA350). July 2015.
- NICE clinical guideline. Psoriasis: assessment and management (CG153). October 2012.
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NHS ENGLAND (POLICY/COMMISSIONING) GUIDANCE

- NHS England. 2013/14 NHS Standard Contract for Specialised Dermatology Services (All ages). A12/S/a.

OTHER GUIDANCE

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ADDITIONAL INFORMATION

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NB: This briefing presents independent research funded by the National Institute for Health Research (NIHR). The views expressed are those of the author and not necessarily those of the NHS, the NIHR or the Department of Health