

## PRESS RELEASE

### **AbbVie welcomes Therapeutic Goods Administration (TGA) Regulatory Approval of SKYRIZI™ (risankizumab)<sup>1</sup>**

**SYDNEY, AUSTRALIA, 23 JULY 2019** – AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, today announced that the Therapeutic Goods Administration (TGA) granted regulatory approval for SKYRIZI™ (risankizumab) for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for phototherapy or systemic therapy.<sup>1</sup>

Psoriasis is a chronic, systemic disease that causes inflamed, red and often scaly patches to form on the skin.<sup>2</sup> It can affect many aspects of a person's life and can negatively impact a person's long-term health and quality of life. It can be associated with other health conditions, such as hypertension, diabetes, cardiovascular disease and depression.<sup>2-3</sup> The highly visible nature of the disease can be psychologically distressing. Patients often experience embarrassment, lack of self-esteem, anxiety and are at an increased risk for depression.<sup>2</sup>

Psoriasis affects an estimated 450,000 people in Australia<sup>4</sup> and 125 million people worldwide and reports suggest that its prevalence may be on the rise, making it a growing serious global health concern.<sup>2-3</sup>

Plaque psoriasis is the most common form of the disease.<sup>2-3</sup> It has been reported that many patients with moderate to severe plaque psoriasis are undertreated and a large portion do not achieve and maintain high-levels of skin clearance.<sup>5-6</sup> More than 80 percent of patients with moderate to severe psoriasis are treated only with topical therapy or are not treated at all, according to the Multinational Assessment of Psoriasis and Psoriatic Arthritis Survey that was published in 2014.<sup>6</sup>

There has been significant progress in the psoriasis treatment landscape, including biologic therapies, which have improved outcomes for patients with moderate to severe plaque psoriasis.<sup>7-8</sup> However, there are still many patients who do not achieve an adequate level of skin clearance, symptom relief or improvements in quality of life.<sup>9</sup>

"The approval of SKYRIZI is an important milestone for the treatment of moderate to severe plaque psoriasis and we are pleased to be able to offer patients in Australia a new treatment option" said Kirsten O'Doherty, Vice President and General Manager Australia and New Zealand.

Currently SKYRIZI™ (risankizumab) is not listed on the Pharmaceutical Benefits Scheme (PBS) for patients with Chronic Plaque Psoriasis (CPP).

"It is important for physicians to have multiple treatment options available, including products with different mechanisms of action, to help provide patients with a management plan that's



right for their condition. We are working to ensure access to this new treatment is available via the Pharmaceutical Benefits Scheme at the earliest opportunity,” Ms. O’Doherty said.

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

### **About SKYRIZI (risankizumab)<sup>1</sup>**

SKYRIZI (risankizumab) is an interleukin 23 (IL-23) inhibitor and is indicated for the treatment of moderate to severe plaque psoriasis in adults (18 years or older) who are candidates for phototherapy and systemic therapy.

### **Important Safety Information<sup>1,10</sup>**

SKYRIZI must not be used if the patient has an allergy to risankizumab or any of its ingredients. In addition, it must not be used if the patient has an active infection which the doctor thinks is important. If the patient currently has an infection, or has had an infection that keeps coming back, their healthcare professional should be informed before using SKYRIZI.

Prior to using SKYRIZI, patients should be checked for tuberculosis (TB) infection. SKYRIZI must not be given to patients with active TB. Patients receiving SKYRIZI should be monitored for signs and symptoms of active TB. Treatment for TB should be considered prior to using SKYRIZI 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 SKYRIZI, completion of all appropriate immunisations should be considered according to current immunisation guidelines. SKYRIZI should not be used with live vaccines.

Common side effects include upper respiratory infections with symptoms such as a sore throat and stuffy nose, feeling tired, fungal skin infection, injection site reactions, headache, small raised red bumps on the skin.

Please review the Consumer Medicines Information [here](#) for further safety information on SKYRIZI.

### **About AbbVie**

AbbVie is a global, research and development-based 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



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